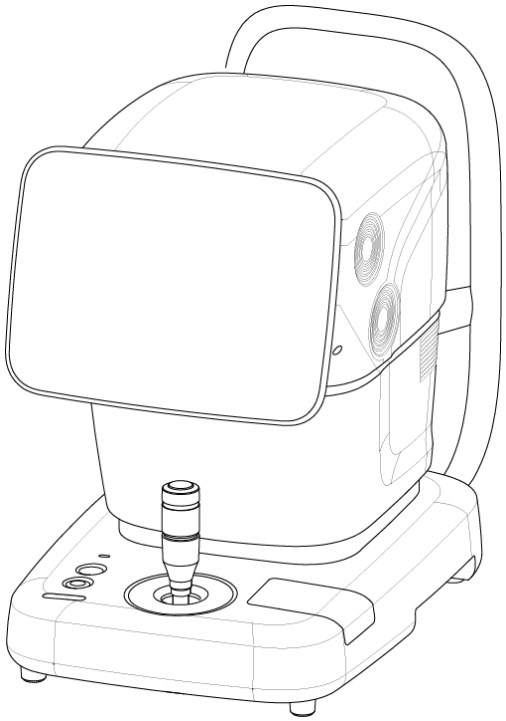
INSTRUCTION MANUAL

OPTICAL BIOMETER

OA-2000



Read this manual thoroughly before using the instrument to ensure proper and safe operation. Contact Tomey Corporation or our local distributor if you have any questions or you encounter any problems during operation.

Note

- ***Always follow the operation procedures described in this manual.***
- ***Keep this manual in a readily accessible location while operating the instrument.***
- ***Contact our local distributor if you lose this manual.***

VIEWLIGHT
POWERED BY INNOVATION

TOMEY

683A9090-0H

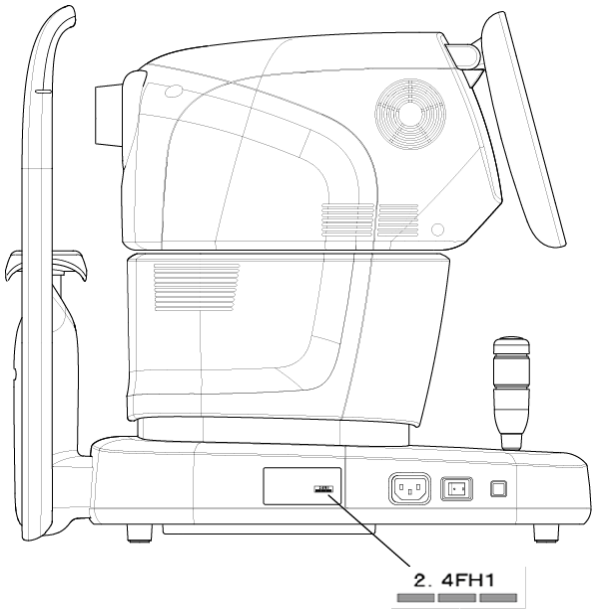
i Important Safety Information

- ***Do not install this instrument in a location where explosives or inflammable substances are used or stored. Otherwise, fire or explosion may occur..***
- ***Do not remove the cover of the instrument. You may be directly exposed to high voltage sections.***
- ***Do not disassemble or modify the instrument. You may be directly exposed to high voltage sections.***

- ***Disconnect the power cord from the instrument before servicing the instrument. Otherwise, you may get an electric shock.***

- ***Do not place water or chemicals on the instrument. Any water or chemicals entering the instrument may cause an electric shock or failure.***
- ***Only use the specified terminal for connection of the instrument. Using another type of terminal may result in failure of the instrument.***
- ***This instrument is a diagnostic/measuring device specially designed for ophthalmology. Never use the instrument for other purposes.***
- ***The external output terminal is not isolated from the internal circuit. Inappropriate wiring may damage the internal circuit. Be sure to contact Tomey Corporation beforehand when using the external output terminal.***

■ ***This device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. The antenna used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operated in conjunction with any other antenna or transmitter.***



ii How to read this manual

Outline

This manual is structured as follows.

1. PRIOR TO USE
Describes safety precautions and important information to be understood before installing and using the instrument.

2. NAMES AND FUNCTIONS
Describes names and functions of each section of the instrument.

3. OPERATION PROCEDURES
Describes information required for installing and using the instrument.

4. TECHNICAL INFORMATION
Describes useful technical information about the instrument.

5. INSPECTION AND MAINTENANCE
Describes procedures for replacing consumable parts, etc. that the user of the instrument should normally conduct.

6. TROUBLESHOOTING
Describes how to solve problems.

7. CONSUMABLES AND OPTIONAL EQUIPMENT
Describes consumable parts and optional equipment.

8. Specifications
Describes the specifications of the instrument.

SYMBOLS USED IN THIS MANUAL

Descriptions accompanied by the symbols below indicate the following:

■ ***This is a precaution that, if unheeded, will result in a hazardous situation where there is an imminent danger of serious injury or death.***

■ ***This is a precaution that, if unheeded, could result in a hazardous situation where there is a possibility of serious injury or death.***

■ ***This is a precaution that, if unheeded, may result in a situation where there is a possibility of minor or moderate injury or damage to property.***

■ ***This is additional information which may contain special precautions on company policies related, either directly or indirectly, to the safety of personnel or to the protection of property.***

iii Contents

1. PRIOR TO USE

Note

- ***Read this manual thoroughly before using the instrument to ensure proper and safe operation.***
- ***Always follow the operation procedures described in this manual.***
- ***Check that there are no devices that generate strong magnetic field near the instrument. A strong magnetic field may cause noise and affect measurement.***

1.1 Precautions for operation

- ***Only allow qualified operators to use the instrument.***
- ***When measuring the axial length, fully examine the measured data for waveforms and variations. If the measurement result is doubtful, perform measurement again or another inspection to review the inspection result. If incorrect measurement data is used to select intraocular lenses, further surgery might be required.***
- ***When using the IOL calculation result to select intraocular lenses, thoroughly determine the selection by also examining cataract surgery methods and other inspections.***
- ***When measuring corneal thickness, the measurement accuracy may exceed ±5μm depending on the conditions of measurement or patient's cornea. Carefully consider the history of corneal diseases and surgeries, and review the inspection result by performing measurement again or another inspection if the measurement result is doubtful.***
- ***An artifact may occur during ultrasound measurement. If measurement value is doubtful, consider waveforms and other examinations to carefully determine whether to adopt the value.***
- ***Precautions when installing the instrument***

- *Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause an electric shock or failure.*
- *Do not install the instrument in a location where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and result in fire.*
- *Check that the frequency, voltage, and allowable current (or power consumption) of the power source are appropriate. Otherwise, fire or electric shock may occur.*
- *Connect the power plug to a grounded 3-pin outlet. Otherwise, a short circuit due to failure of the instrument may result in electric shock.*
- *Do not place any heavy object on the power cord or squash the power cord. Fire or electric shock may occur.*
- *Fully insert the power plug into the outlet. Faulty contact, allowing any metal to contact the exposed terminal of the plug, or dust accumulated on the exposed terminal of the plug may result in fire or electric shock.*

- *When operating this instrument connected to other devices, only use devices that comply with IEC60601-1 or that comply with IEC60950-1 and whose power source is isolated with an isolation transformer. Furthermore, all devices should be configured to comply with the standard IEC60601-1 ME system. Anyone who connects any additional device to the communication connector will be considered a person configuring a medical system, and is therefore responsible for complying with the requirements of an IEC60601-1 ME system. Contact Tomey Corporation or our local distributor before connecting the instrument with a communication connector.*
- *Do not connect a device with data transmission specifications that are not compatible. Fire or electric shock may occur.*
- *Conduct grounding work correctly. Otherwise you may get an electric shock.*

- *Do not hold the head, chin rest, forehead pad, or joystick when moving the instrument. These components are detachable and the instrument may drop, resulting in injuries.*
- *Install the instrument in a location not subject to direct sunlight, high temperature and humidity, or air containing dust, salt, and/or sulfur. Otherwise, failure or malfunction may occur.*
- *Install the instrument in a leveled stable location free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. Also, the instrument may topple over or fall down, resulting in fire or a serious accident.*
- *Install the instrument between the patient and physician so that they can face each other.*
- *Install the instrument in a location with ample clearance from other devices to allow smooth inspection.*
- *Check the battery power source (discharge condition, polarity, etc.).*

■ *Precautions before using the instrument*

- *Check the electrical contact of switches, polarity, dial setting, and meters, and that the instrument is working correctly.*
- *Check that all cables are connected correctly.*
- *Since simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation, exercise caution when using this instrument.*
- *Check the sections that the patient will directly touch.*
- *Peel off the top sheet of chin rest paper and clean the forehead pad with a cloth dampened with alcohol before conducting measurements.*
- *Check the battery power source (discharge condition, polarity, etc.).*
- *Check that the instrument is correctly grounded.*
- *Check that the date set in the instrument conforms to the actual operation date and time.*

■ *Precautions during operation*

- *Do not place any container with liquid in it on the instrument. Any liquid entering the instrument may cause electric shock or failure.*
- *Be sure to touch the “New” button to delete the measurement data for the previous patient before measuring a new patient. If new measurement is started without deleting the previous data, the measurement data for the previous patient may be included.*
- *Do not allow the patient to touch the terminals for connecting the instrument to external devices.*

- *When moving the measuring head and/or chin rest of the instrument, pay attention to the position of the patient's face, hands, and fingers. The patient may be injured by the moving section of the instrument.*
- *Do not allow any person to place their hands or fingers in the clearance under the measuring head or the section under the chin rest. Their hands or fingers may be caught and injured.*
- *Do not lean on the instrument or press the instrument from the top. The instrument may topple over, resulting in mechanical failure or injuries.*
- *Be careful to not exceed the time and quantity limit required for diagnosis, medical treatment, and measurement.*
- *Constantly observe that both the instrument and patient are free of problems.*
- *If a problem with the instrument or the patient occurs, take appropriate action, such as stopping the device, to ensure the patient’s safety.*
- *Do not allow the patient to touch the instrument.*
- *If problems such as smoke, offensive odor, or abnormal sound occur, immediately turn off the instrument, disconnect the power plug from the outlet, and contact Tomey Corporation or our local distributor.*

■ *Precautions after operation*

- *Do not place any container with liquid in it on the instrument. Any liquid entering the instrument may cause electric shock or failure.*

- *Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. Fire or electric shock may occur. (These solvents may also corrode the resin or coating on the cover of the instrument.)*
- *Follow the specified procedures to return the operation switch, dial, etc. to their original positions and turn the instrument off.*
- *Hold the plug when disconnecting the power plug from the outlet to avoid placing excessive force on the cord. Pulling the cord may damage the inner core wires, resulting in electric shock or fire.*
- *When disconnecting cords, do not apply too much force on them, for example, do not hold and pull the cord.*
- *Refer to "5.6 Storing" for instructions on the storage of the instrument.*

- *Clean the instrument at the end of operation in preparation for the next use.*
- *Clean and neatly arrange the accessories and cables.*

■ ***If any failure occurs in the instrument, immediately stop operation, indicate the failure in the instrument, and contact our local distributor for repairs.***

- *Do not modify the instrument. Doing so may cause electric shock or failure of the instrument. There is a high-voltage section in the instrument. Touching this section will result in death or serious injuries.*
- *Disconnect the power cord from the outlet when replacing fuses. Otherwise, you may get an electric shock, resulting in death or serious injuries.*

- *Use the power cord and fuses provided with the instrument or specified by Tomey to ensure safety. Also, do not use the accessories provided with the instrument for other equipment.*

- *When any failure occurs in the instrument, indicate the failure in the instrument and contact our local distributor for inspection and repairs. Do not attempt to repair the instrument yourself.*
- *Conduct regular inspections of the instrument and components.*
- *When the instrument is not used for 1 month or longer, check that the instrument is operating correctly and safely before starting operation. Refer to "5.3 Inspection" in this manual for the checking procedures.*

1.2 Checking package contents

Open the package and check that the required quantity of the following items is included and they are not damaged. If any item is missing or damaged, contact our local distributor as soon as possible.

Note

■ ***Keep the box and packing materials for use when moving or transporting the instrument.***

■ ***When taking the instrument out of the box, pull the outer box upward and then remove the packing materials. Be careful not to lift the instrument by directly holding the measuring head, chin rest, forehead pad, or joystick. The instrument may be damaged.***

- Main unit Optical Biometer OA-2000 1
- Power cord 1
- Model eye 1
- Touch pen 1
- SD card (installed in the main unit) 1
- Fuses (2 fuses are installed in the main unit) 4
- Chin rest paper 1
- Pins for chin rest paper 2
- Printer paper (1 paper is installed in the main unit) 2
- Dust cover 1
- INSTRUCTION MANUAL (this manual) 1
- DATA Transfer installation CD 1
- DATA Transfer Starting Guide 1

The following parts are optional

- OKULIX USB dongle 1

1.3 Glossary

[A.A]	:	Auto Alignment / Auto Measurement
[ACD]	:	Anterior chamber depth measurement
[Acryl]	:	Acrylic lens
[A.M]	:	Auto Alignment / Manual Measurement
[Aphakic]	:	Aphakic eye
[Avg]	:	Average value
[AX]	:	Astigmatism axial anlge [0° - 180°] Represents the direction where a degree of astigmatism is present; the degree will be applied where it intersects at right angles with the astigmatism axis.
[Axial]	:	Axial length measurement (biometry)
[BD address]	:	Bluetooth® Device Address Number set to each device to identify the connection
[Bluetooth®]	:	Near Field Communication
[Caliper]	:	Manually moves the measurement point.
[CCT]	:	Corneal center thickness
[CCT (Ultrasound)]	:	Ultrasound correction for corneal thickness The reference value expected when measuring the same corneal thickness using our ultrasound pachymeter (SP-100, etc.).
[Contact]	:	Displays the value calculated by the AL-3000 contact lens conversion formula.
[CYL]	:	Cylindrical refractive power [D]
[D]	:	Diopter The unit of refractive power representing the level of myopia, hyperopia, or astigmatism. Reciprocal of the focal length measured in meters.
[Data Transfer]	:	System to output inspection data from Tomey products to digital files.
[Easy IOL]	:	Name of IOL power calculation software
[Export]	:	Transmits measurement data to TOMEY Link.
[Immersion]	:	Displays the value calculated by the AL-3000 immersion conversion formula.
[IOL]	:	Intraocular lens

[K1]	:	Radius of corneal curvature of minor meridian [mm] or corneal refractive power (D)
[K2]	:	Radius of corneal curvature of major meridian [mm] or corneal refractive power (D)
[KAI]	:	(Kerato-asymmetry Index) Index showing asymmetry of corneal shape obtained by keratometer measurement. An index is calculated for an ellipse obtained by calculation of keratometer measurement according to misalignment between the center of the ellipse and alignment position (almost the center of the optical axis). As this index gets larger, the ellipse deviates from the ring projected onto the eye during keratometer measurement and it is more probable to be irregular astigmatism of keratoconus etc.
[KI]	:	Cornea equivalent refractive index (Keratometric Index)
[KRI]	:	(Kerato-regularity Index) Index showing regularity (irregularity) of corneal shape obtained by keratometer measurement. An index is calculated from misalignment between an ellipse obtained by calculation of keratometer measurement and a ring projected onto an eye subject to keratometer measurement. As this index becomes larger, the projected ring is not a proper ellipse and it is more probable to be higher order irregularity of keratoconous which cannot be corrected with optical glass lens.
[M.A]	:	Manual Alignment / Auto Measurement
[M.M]	:	Manual Alignment / Manual Measurement
[OKULIX]	:	IOL power calculation software that uses the ray tracing method.IOL power calculation software that uses the ray tracing method. We install this software in OA-2000 as an import agent.
[OPT]	:	Optical axial length measurement
[OptLength]	:	Optical distance from the tear to the retinal pigment epithelium.
[Pachy]	:	Corneal thickness measurement
[Phakic]	:	Phakic eye
[PL]	:	Abbreviation of POST LASIK
[PMMA]	:	Eye with a PMMA lens inserted
[Post]	:	After refractive power correction surgery.
[Pre]	:	Before refractive power correction surgery.
[Pupil]	:	Shows the pupil diameter in [DIA] mode for corneal diameter measurement/pupil diameter measurement.
[SNR]	:	Signal to noise ratio. A larger value represents large interference signal, meaning higher quality signals can be obtained.

[SPH]	:	Spherical refractive power [D]
[TOMEY Link]	:	Digital medical record system to manage data measured with Tomey products.
[VD (vertex distance)]	:	Distance between corneal vertexes [mm] Represents the distance between the corneal vertex and the posterior surface of the lens to be prescribed. When (VD=CL), vertex distance is calculated as 0 mm.
[WTW]	:	Shows the corneal diameter in the [DIA] mode for corneal diameter measurement/pupil diameter measurement.
[Auto Alignment]	:	Function to automatically align the sight in the up/down/right/left/focus directions.
[Caliper]	:	Manually move the measurement point.
[Gain]	:	Adjusts amplification and amplitude of waveforms.
[Gate]	:	Specifies the range of waveforms to be detected.
[Retake]	:	Deletes the data for the displayed eye.
[Silicone]	:	Eye with a silicon lens inserted
[Power-save]	:	Function to automatically turn the LCD off, with only the power lamp flashing, when the instrument is not operated for the specified time (Auto Power Off mode). Touch any button to return to Normal mode.
[Measurement point]	:	Indicates the point where corneal thickness is measured by diameters and angles.
[Touch Alignment]	:	When directly touching the screen, the measuring head moves so that the touched point is displayed in the center of the screen. This allows you to focus the sight in the up, down, left, and right directions without using the joystick.
[Touch panel]	:	Allows you to make various settings and execute the touch alignment function by directly touching the monitor.
[Fitting formula]	:	Converts axial length measurement data in optical method to that in ultrasound method.
[Rx only]	:	This symbol on the label of this device states "Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner."

1.4 Overview

This instrument is an ophthalmology device used to measure the length of living tissues utilizing light interference technology and to measure the cornea on captured images. This device is designed to measure the axial length, anterior chamber depth, corneal thickness, crystal lens thickness, radius of corneal curvature, and corneal shape at optical clinics. In addition, this instrument is equipped with a communication function for receiving and displaying measurement results from another ultrasound device that measures axial length or corneal thickness.

With an IOL power calculation function, this instrument has various IOL power formulae applicable to ordinary cataract surgery and/or cataract surgery of eyes with corrected corneal refractive power, and provides data necessary to determine IOL power.

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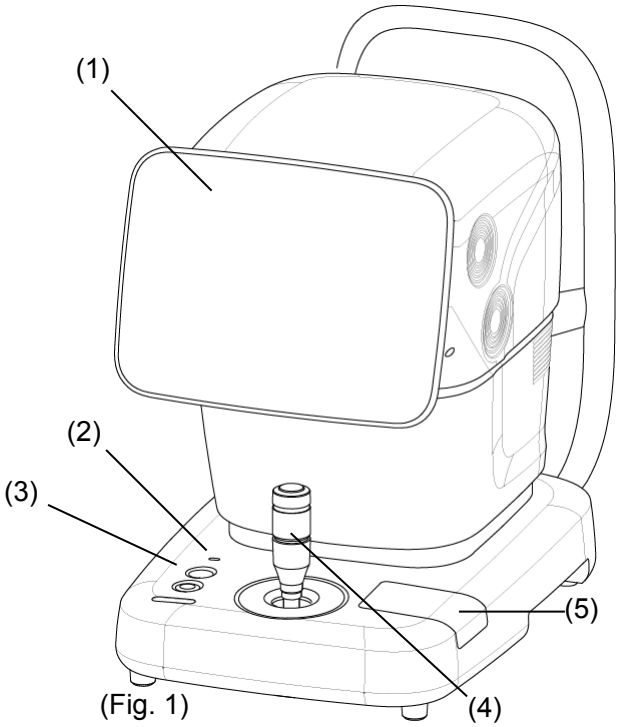
2. NAMES AND FUNCTIONS

2.1 Physician's side



(Fig. 1)

(1) LCD and touch panel
Displays the data or used to perform operations. The display angle can be adjusted.

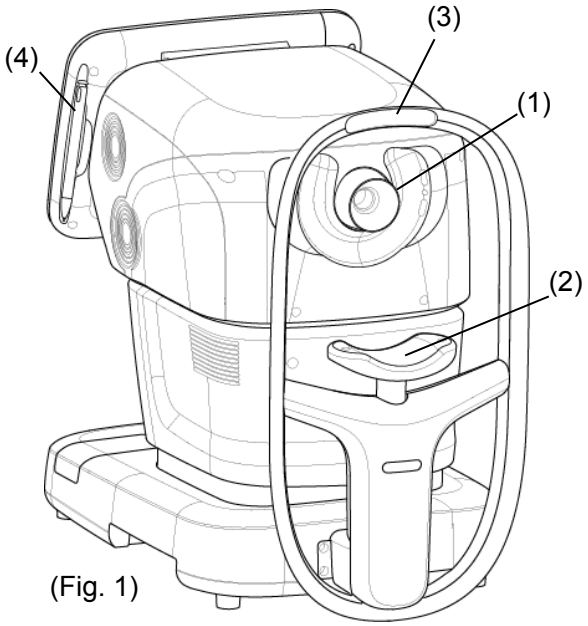
(2) Power lamp

(3) Chin rest up/down button

(4) Joystick
Moves the head in all directions. A measurement button is provided on the top.

(5) Built-in printer

2.2 Patient's side



(Fig. 1)

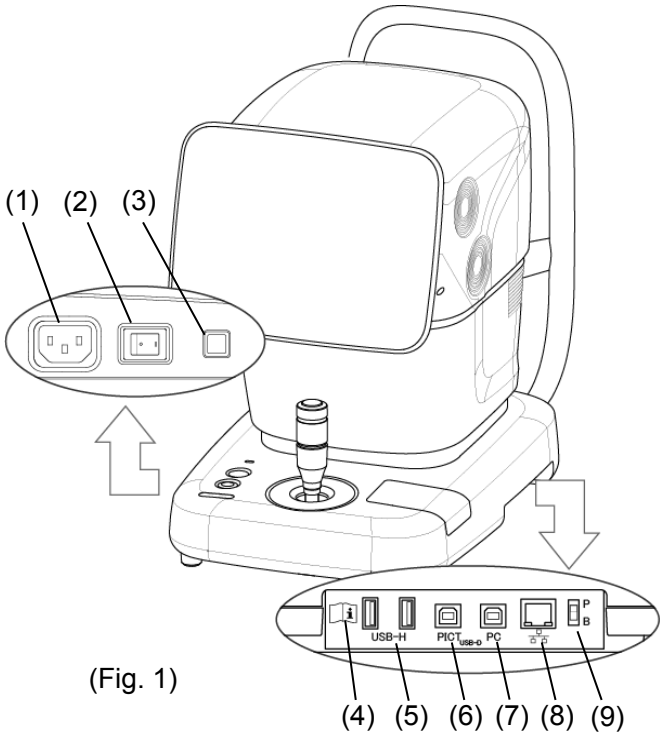
(1) Measurement window

(2) Chin rest

(3) Forehead pad

(4) Touch pen
The touch pen holder is a magnet type.

2.3 Sides of the main unit



(Fig. 1)

(1) Power socket

(2) Power switch

(3) Packing button
Pressing this button for 3 seconds moves the head to a set position in preparation for packing.

(4) SD card slot

(5) USB-H connector
Connector for measurement unit, USB flash memory, and external ID input device

(6) USB-D connector (PICT)
Connect the PictBridge printer here.

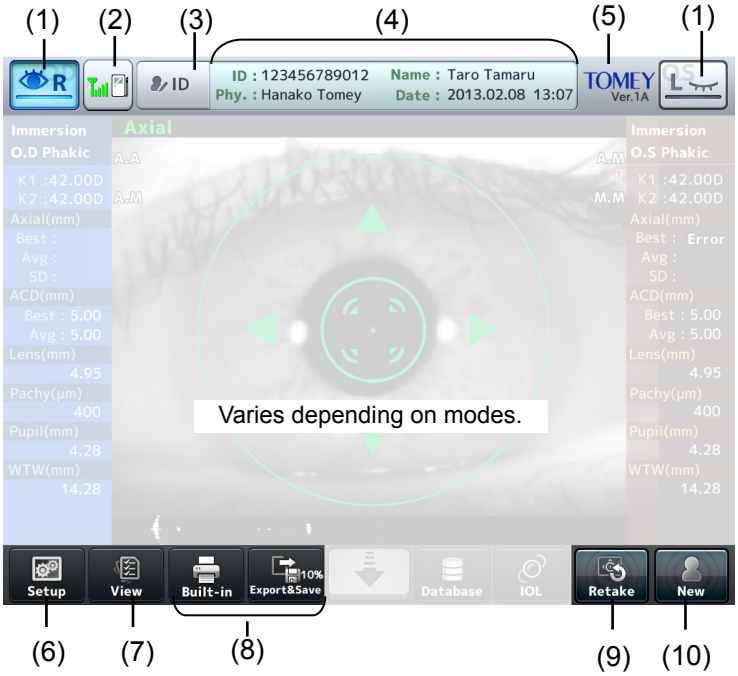
(7) USB-D connector (PC)
Connect the personal computer, etc. here.

(8) LAN connector

(9) Maintenance switch
Our service personnel use this switch for maintenance. Do not change the setting.

2.4 Screen

2.4.1 Basic structure and common items



(1) Eye display field (eye selection button)

(2) AL-4000 communication status field
The status of communication with AL-4000 is displayed with icons.

Communicating via wireless access	Communicating via USB	Communication stopped	COMMUNICATION NOT POSSIBLE *
			

* Operation not possible. Utility operations are required for connection.

(3) "ID" button
Opens the patient information input screen.

(4) Patient information field

(5) Version
The version of the software installed in this instrument is displayed.

(6) "Setup" button
Displays the setting screen.

(7) “View”/”Measure” button
“View” button on the measurement screen and “Measure” button on the view screen

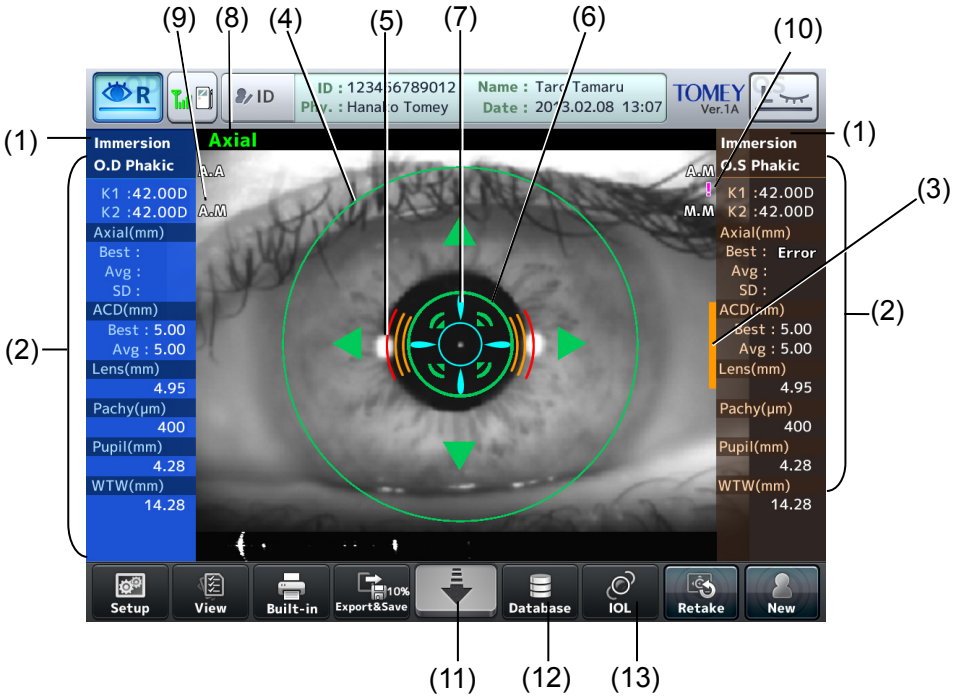
(8) Print, Export & Save buttons

(9) "Retake" button
Deletes the measurement data currently displayed and measures the same eye again.

(10) “New” button

2.4.2 Screens in optical mode

a) Measurement screen



(1) Inspection eye display field

(2) Measurement data display

(3) Measuring head position limit
Appears when the measuring head is near the limit of its movable range. The bar appears at the top, bottom, right, or left of the screen according to the position of the measuring head.

(4) Auto Alignment ring
Indicates the effective range of Auto Alignment.

(5) Focus indicator
Displays the distance between the measuring head and the patient's eye.

(6) Auto Alignment mark

(7) Alignment OK mark

(8) Measurement item
Item being measured flashes.

(9) Auto/Manual
Measurement modes (Auto or Manual) for keratometer measurement data and axial length measurement data are displayed. The first letter represents the alignment mode and the second letter represents the measurement mode.
A.A: Auto Alignment / Auto Measurement
A.M: Auto Alignment / Manual Measurement
M.A: Manual Alignment / Auto Measurement
M.M: Manual Alignment / Manual Measurement

(10) Low reliability mark

Any of the following symbols appear when the number of low reliability data sets exceeds the majority.
When low reliability data sets have exceeded the majority: “!” in white
When reliability of all data is low: “!” in pink
When there are multiple higher peaks detected in the axial length measurement: “!” is shown in pink.
When all data returns an error: error
The reliability mark is shown beside the keratometer measurement and axial length measurement in the measurement data display field.

(11) Head retreat button

The head retreats while this button is touched.

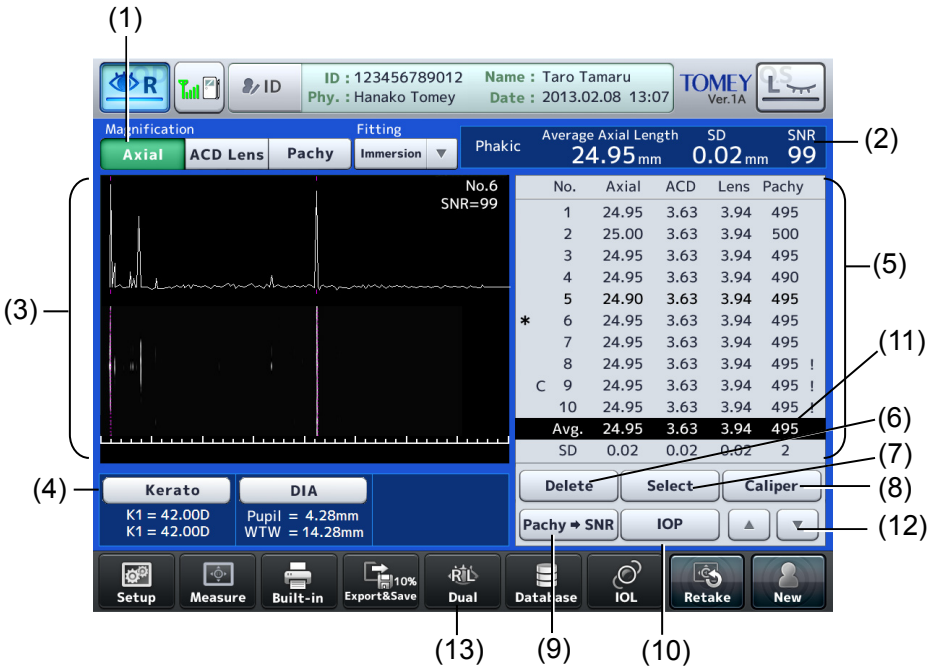
(12) “Database" button

Displays the data management screen.

(13) “IOL” button

Opens the IOL power calculation screen.

b) Axial length view screen



(1) Display area selection button
Enlarges and displays the image of the selected section.
Axial length / anterior chamber depth, lens / corneal thickness.

(2) Axial length measurement data display

(3) Scanned image / waveform display area

(4) View screen switch button

(5) Measurement data display
Lists measurement data of axial lengths, anterior chamber depth, lens, and corneal thickness, and the relevant averages, and standard deviations.

(6) "Delete/Restore" button
Deletes and recovers the measurement data.

(7) "Select" button
The measurement data at the cursor position is selected to be used for calculating IOL power. The selected measurement data is indicated by an "*".

(8) "Caliper" button

(9) "Pachy -> SNR" switch button

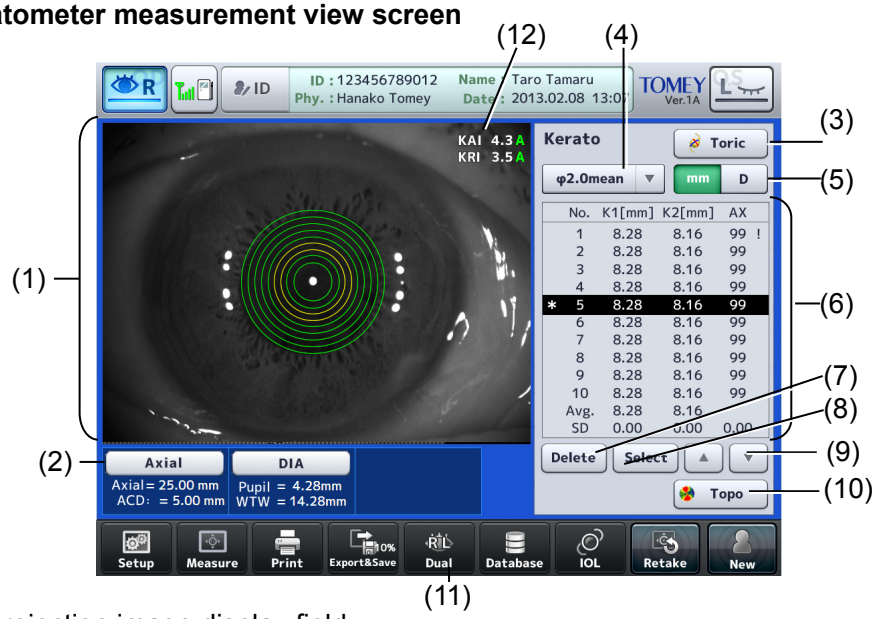
(10) "IOP" button

(11) Selection cursor

(12) Selection cursor UP/DOWN buttons

(13) "Dual" button
Displays the R/L alignment display screen.

c) Keratometer measurement view screen



(1) Ring projection image display field
An image with rings projected is displayed.

(2) View screen switch button

(3) “Toric” button
Displays the toric auxiliary functions.

(4) Measurement position display selector
Select the measurement position to be displayed.
ϕ2.0mean / ϕ2.5 / ϕ3.0
When “ϕ2.0mean” is selected, only the average is displayed.

(5) Unit selector
Select the unit for indications.
mm / D

(6) Measurement data display
K1, K2, AX, and their averages and standard deviations are displayed.

(7) "Delete/Restore" button
Deletes and recovers the measurement data.

(8) "Select" button
The measurement data at the cursor position is selected to be used for calculating IOL power. The selected measurement data is indicated by an “*”.

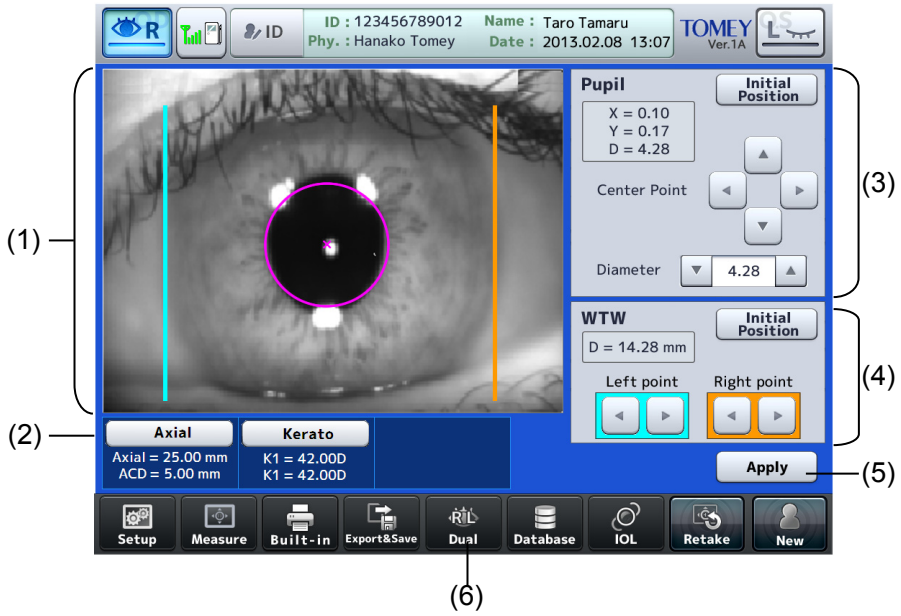
(9) Selection cursor UP/DOWN buttons

(10) "Topo" button
Displays the TopoMap screen.

(11) “Dual” button
Displays the R/L alignment display screen.

(12) KAI/KRI
KAI represents asymmetry of the corneal shape and KRI represents regularity (irregularity) of the corneal shape.

d) Pupil diameter and corneal diameter view screen



(1) Image display field

(2) View screen switch button

(3) Pupil diameter

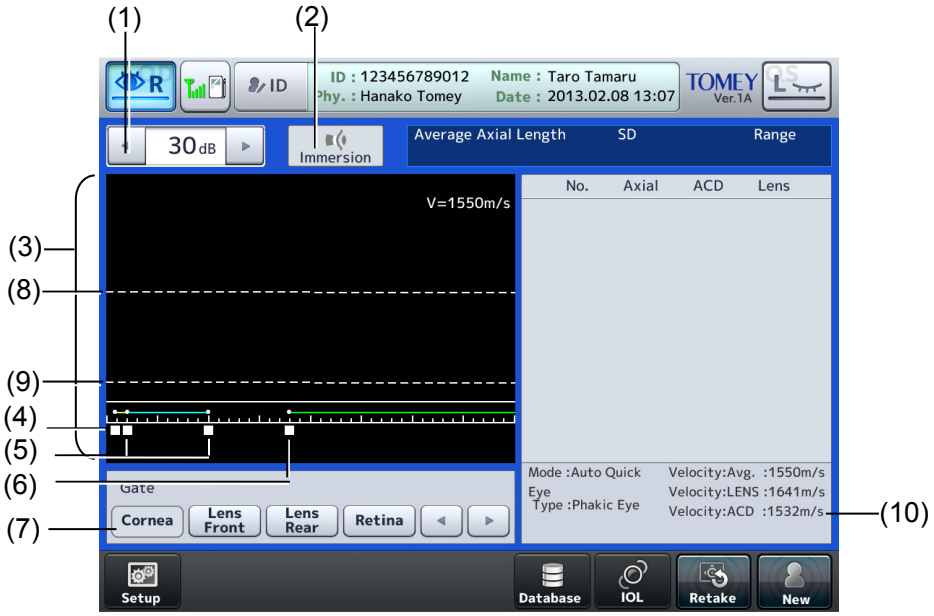
(4) Corneal diameter

(5) "Apply" button

(6) “Dual” button
Displays the R/L alignment display screen.

2.4.3 Screens in each ultrasound mode

a) Axial length measurement screen



(1) Gain display/adjustment field

(2) Mode display – Contact/Immersion

(3) Waveform display area

(4) Corneal gate cursor (only in immersion mode)
The waveform on the right of this cursor position is measured as the waveform of the cornea.

(5) Lens gate cursor
The waveform between these two cursors is the waveform of the lens.

(6) Retina gate cursor
The waveform on the right of this cursor position is measured as the waveform of the retina.

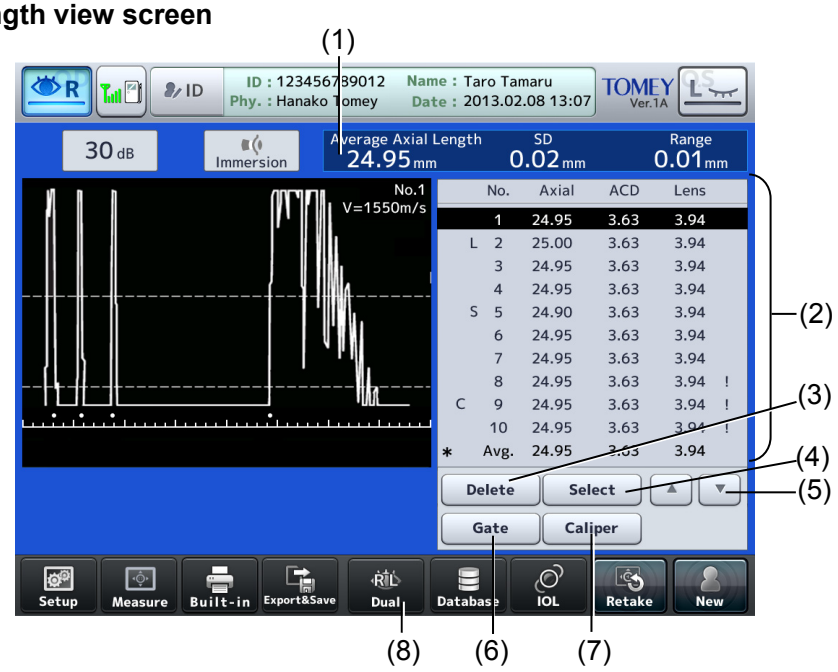
(7) Gate cursor movement button
Moves the gate cursor.

(8) Level cursor/level line
Measurement data will be taken when the waveform rises above this cursor/line position.

(9) Measurement cursor/measurement line
The distance at this cursor/line should be taken as the measurement data.

(10) Measurement conditions display field

b) Axial length view screen



(1) Axial length measurement data display
Displays measurement conditions and measured axial length.

(2) Measurement data display
The axial length, anterior chamber depth, lens, and their average values are listed.

(3) "Delete/Restore" button
Deletes and recovers the measurement data.

(4) "Select" button
The measurement data at the cursor position is selected to be used for calculating IOL power. The selected measurement data is indicated by an “*”.

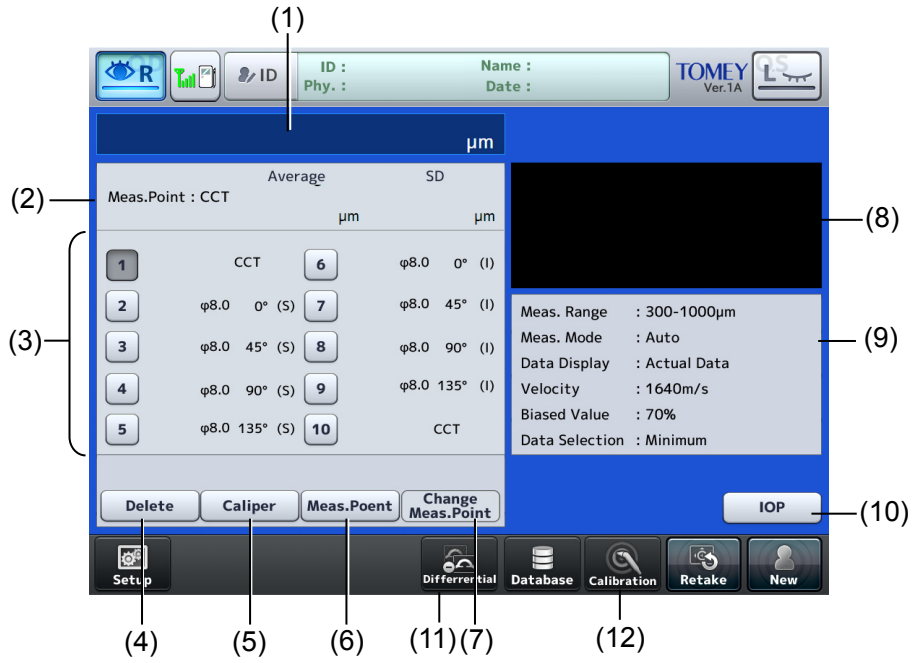
(5) Selection cursor UP/DOWN buttons

(6) “Gate” button

(7) “Caliper” button

(8) “Dual” button
Displays the R/L alignment display screen.

c) Corneal thickness measurement screen



(1) Real-time data display field
Displays the actual measurements of the loaded measurement points. The latest loaded data are displayed during a measurement process.

(2) Corneal thickness data display

(3) Measurement data display

(4) "Delete/Restore" button

(5) “Caliper” button

(6) "Meas Point (measurement point)" button

(7) "Change Meas. Point" button

(8) Measurement waveform display field

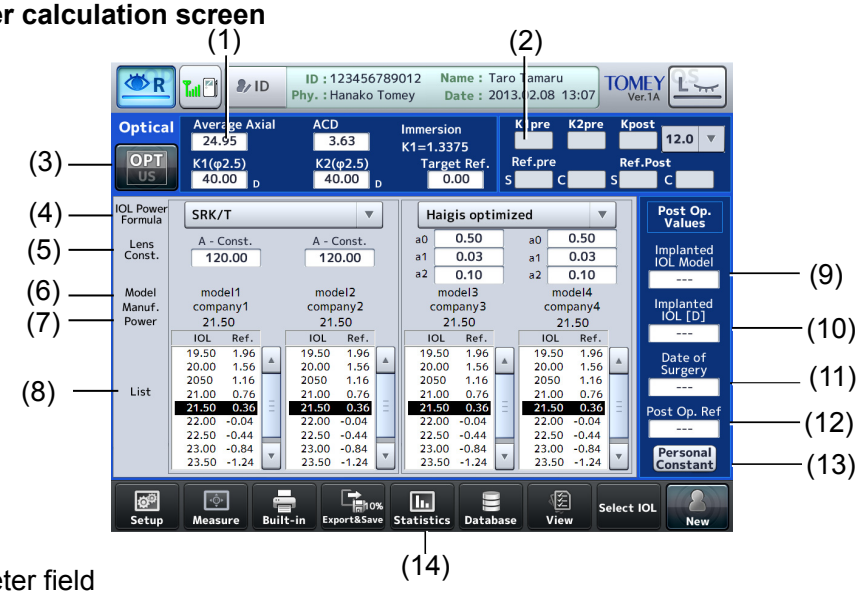
(9) Measurement conditions display field

(10) ‘IOP’ button

(11) "Subtraction" button

(12) “Calibration” button
Calibrates the sensitivity of pachymetry probes.

2.4.4 IOL power calculation screen



(1) Parameter field
Enter the following parameters used for calculating IOL power.
Average Axial (axial length / ACD (anterior chamber depth) / K1 / K2 / Target Ref. (expected refractive power)

(2) Clinical History Method parameter input field

(3) Measurement mode display/measurement data type button
Switches the display between optical measurement data and ultrasound measurement data.

(4) “IOL Power Formula” (formula selection) button
Select a formula for the IOL power calculation here.
Formulae listed in the pull down menu can be set in the system setup. (Refer to “3.9.3 b) Selecting IOL power formula.”)

(5) Lens Const. (lens constant) input field
Displays various optical lens constants corresponding to the adopted IOL power formula.

(6) Model and maker name

(7) IOL Power display field
Displays the calculated IOL power that satisfies the entered “Target Ref.”

(8) List (IOL data list display) field
The IOL standards based on calculation results and estimated refractive power after surgery to implant the IOL are listed.

(9) Implanted IOL Model input field

(10) Implanted IOL [D] (IOL power) input field

(11) Date of Surgery input field

(12) Post Op. Ref (post-operation eye refractive power) input field

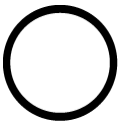
(13) "Personal Constant" screen display button

(14) “Statistics” screen display button

2.5 Symbols used for marking

Refer to instruction manual.

“ON” (power)



“OFF” (power)

Type B applied part

Grounding (earth)

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3. OPERATION PROCEDURES

3.1 Safety precautions

■ ***The power plug completely isolates the instrument from the commercial power source. If there is a problem with the instrument, turn off the power switch and disconnect the power plug. Install the instrument in a place where this can be performed smoothly.***

■ ***Install the instrument so that the user can use the system under optimal conditions. Carefully connect the devices so that the wiring is not disconnected unintentionally during operation, and does not hinder operation of the instrument.***

3.2 Preparation before use

Note ■ ***Be sure to touch the "New" button to delete the measurement data for the previous patient before measuring a new patient. If new measurement is started without deleting the previous data, the data for the previous patient may be included.***

3.2.1 Connections

a) Power code

Insert the connector of the power cord into the power socket on the side of the main unit in the correct direction. Connect all three pins of the plug.

b) Connecting the axial length and corneal thickness measurement instrument AL-4000

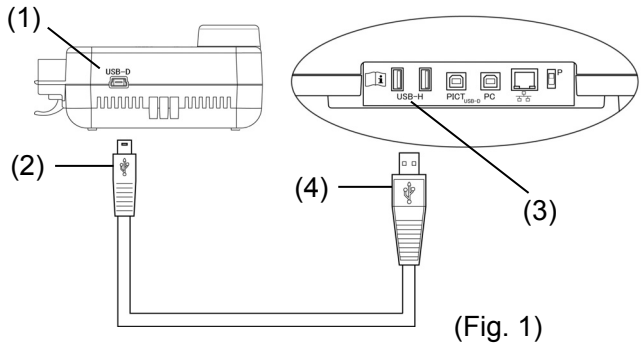
Note ■ ***Check that either or both of connected devices is in new patient mode before starting to communicate the patient information and measurement data. Communication cannot be started while both devices have information and measurement data for the last patient.***

Connection methods with AL-4000 include USB connection (wired) and wireless connection.

[USB connection]

1） Plug the USB cable plug B (2) into the USB-D connector (1) on the top of AL-4000 in the correct orientation.

2） Plug the USB cable plug A (4) into any of the USB-H connectors (3) on the side of the main unit, making sure the orientation is correct.



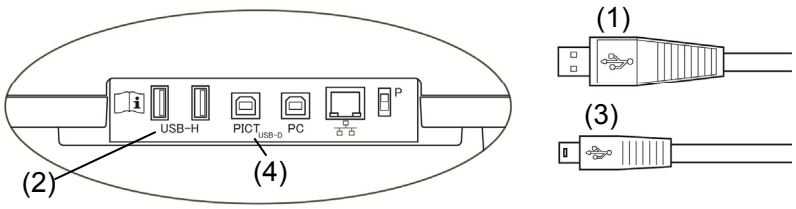
(Fig. 1)

[Wireless connection]

Refer to "3.2.2 Wireless communication connection with the axial length and corneal thickness measurement instrument AL-4000" to make settings.

c) External digital printer

Note ■ ***Use only the specified printer and cables. Use a video signal cable or remote cable to connect this instrument to a device conforming to IEC60601-1 or JIS T 0601-1 or conforming to IEC60950-1 and with a power source isolated by an insulated transformer.***



(Fig. 1)

[Video printer]

1) Insert the cable plug A(1) of the USB-H cable into the USB connector (2) on the side of the main unit in the correct orientation.
2) Connect the other cable plug B (3) of the USB cable to a video printer.

   Follow the instruction manual of the video printer for details on how to connect the printer.

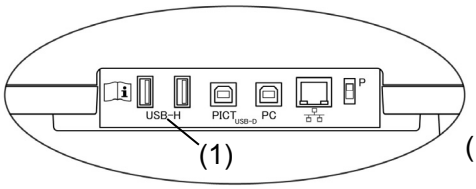
[PictBridge printer]

1) Plug the mini cable plug B (3) of the USB cable into the mini USB-D connector PICT (4) on the side of the main unit in the correct orientation.
2) Connect the other cable plug A (1) or mini A of the USB cable to a video printer.

Refer to the instruction manual of the PictBridge printer for details on how to connect the printer.

d) External ID input device

Plug the connector of the external ID input device (e.g. barcode reader, card reader, keypad, and keyboard) into the USB-H terminal (1) on the side of the main unit, checking the correct orientation.



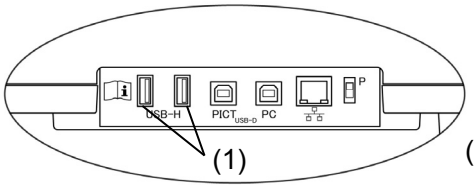
(Fig. 1)

e) Connecting OKULIX USB dongle

Note

- ***Use the OKULIX USB dongle specialized for this instrument included in the package.***
- ***Connect the OKULIX USB dongle directly to the instrument without using an USB hub.***

Connect the OKULIX USB dongle to the USB-H connector terminal (1) on the side of the instrument.



(Fig. 1)

f) Connecting the personal computer

Note

- ***The network support system "TOMEY Link" (optional) or the inspection data receiving software "DATA Transfer" (included in the package) is required for data communication with the Machine.***
- ***Refer to the corresponding operation manual for installation, settings, and operation of TOMEY Link and DATA Transfer.***
- ***Connection setting is required for connecting with TOMEY Link and DATA Transfer. Refer to "3.9.4 d) PC connection settings" to make settings.***
- ***Be sure to make network settings under the consent of your network administrator.***

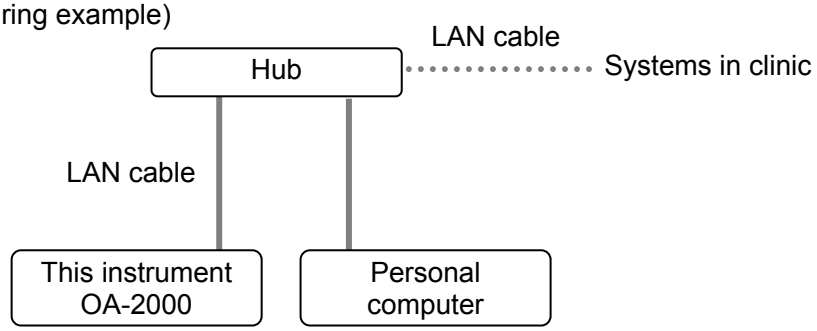
There are two methods to connect with a personal computer: LAN connection and USB connection.

[Connecting LAN cables]

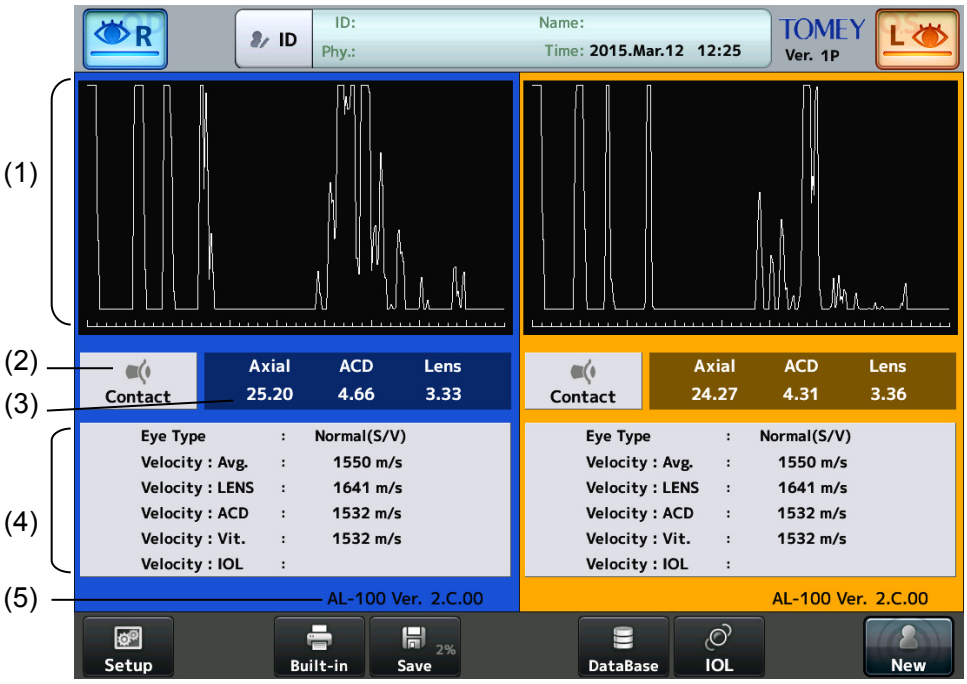
Note ■ ***For LAN connection, be sure to connect the unit to a computer via a hub. The unit does not work correctly of directly connected to a computer.***

Prepare the following items.
- LAN cables (straight type, category 5 or higher) : 2
- A network hub (A 100MHz switching hub recommended) : 1
- A computer with TOMEY Link or DATA Transfer installed : 1

(Wiring example)



g) AL-100 measurement data review screen



(1) Waveform display field

(2) Mode display field – Contact / Immersion

(3) Axial length measurement data field

(4) Measurement condition display field

(5) AL-100 version

h) Connection with Biometer AL-100

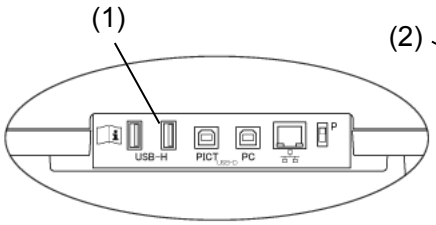
Note ■ ***The following settings are required in Biometer AL-100. . Refer to the Biometer AL-100 instruction manual for the settings.***

BAUD RATE	: 38400
DATA LENGTH	: 8Bit
PARITY	: NONE
STOP BIT	: 1bit

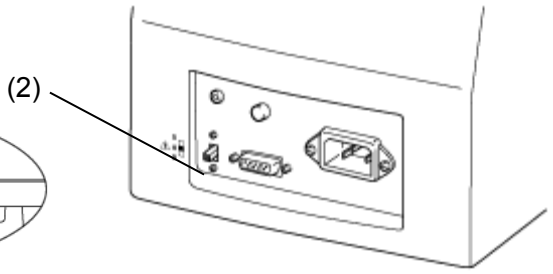
Use a serial cable (Dsub 9 pins, crossover cable, male + female) and USB serial conversion cable for connection.

1) Connect the serial cable and USB serial conversion cable.

2) Insert the USB plug into any of the USB-H connectors (1) on the side of the main unit, and insert the serial cable plug into the Communication Cable Terminal (2) on the back of AL-100.



(Fig. 1 Side of OA-2000)



(Fig. 2 Back of AL-100)

3.2.2 Connecting the axial length and corneal thickness measurement instrument AL-4000

CAUTION

- ***In-house wireless stations, specified low power wireless stations, and amateur wireless stations for wireless frequency identification also use the frequency band used for this instrument's wireless communication. Check that none of these stations are operating near this instrument before use.***
- ***When this instrument causes wireless frequency interference harmful to the in-house wireless station for wireless frequency identification, change the frequency immediately or take other measures to avoid interference. Stop emitting wireless waves and contact Tomey or our local distributor.***
- ***When this instrument causes wireless frequency interference harmful to a specified low power wireless station or amateur wireless station for wireless frequency identification, contact Tomey or our local distributor.***

a) Wireless communication setting

Refer to "3.9.4 e) AL-4000 wireless settings" to make the settings.

b) Connection for wireless communication

Note

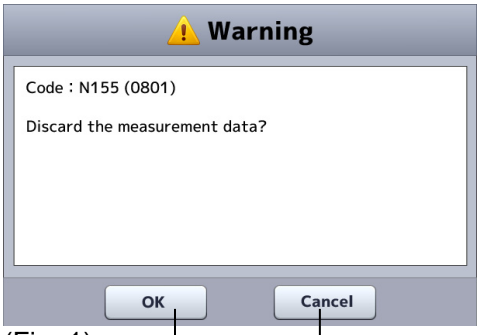
- ***Check that either or both of connected devices is in new patient mode before starting to communicate the patient information and measurement data. Communication cannot be started while both devices have information and measurement data for the last patient.***
- ***When connecting a device with a USB cable during wireless communicating, wireless connection is changed to wired connection.***

[Automatic connection upon startup]

When the AL-4000 is selected as the "connection place" in this instrument, wireless communication automatically starts when both the AL-4000 and this instrument are turned on. However, if the AL-4000 has already started wireless communication with another device, this instrument cannot start wireless communication.
Refer to "3.9.4 e) AL-4000 wireless settings" for how to set "automatic connection upon startup." Refer to the instruction manual of the AL-4000 for how to set the AL-4000.

[No communication state]

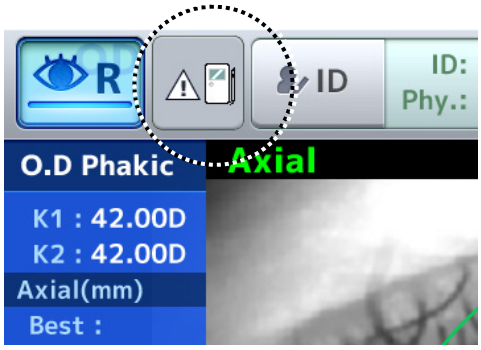
The confirmation screen appears if measurement data remains in this instrument when attempting to connect to the AL-4000 in new patient mode. (Fig. 1)
Click the "OK" button (1) to delete the data in this instrument and connect to the AL-4000.
Click the "Cancel" button (2) to stop communication. (Fig. 2)



(Fig. 1)

(1)

(2)



(Fig. 2)

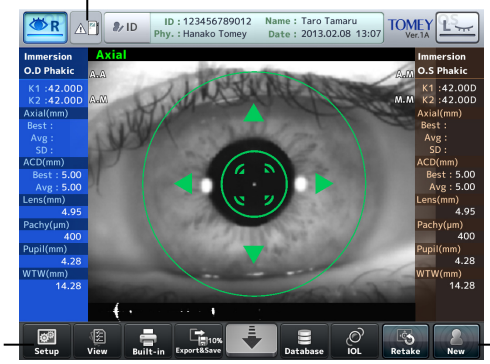
[Resuming communication from the no communication state]

1) Click the “New” button (1) to clear the existing data.

2) Select the same measurement mode as that of the AL-4000 using the “Setup” button (2).

3) Click the “AL-4000 communication check” button (3) to resume communication.

(3)



(2)

(1)

(Fig. 3)

3.2.3 Turning the power on and adjustment after turning the power on

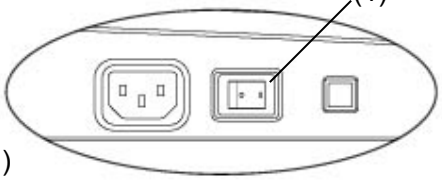
a) Turning the power on

Note ■ ***To restart the system, turn the power off, wait for ten seconds or so, and turn it on again.***

1) Turn on the power switch (1) on the side of the main unit.

2) The startup screen (Fig. 2) appears and then displays the optical measurement screen.

(1)



(Fig. 1)

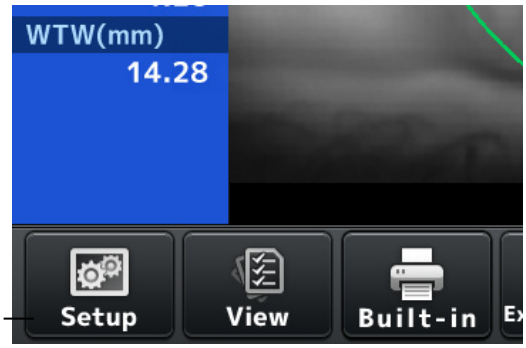
(Fig. 2)

b) Adjustment after turning power on

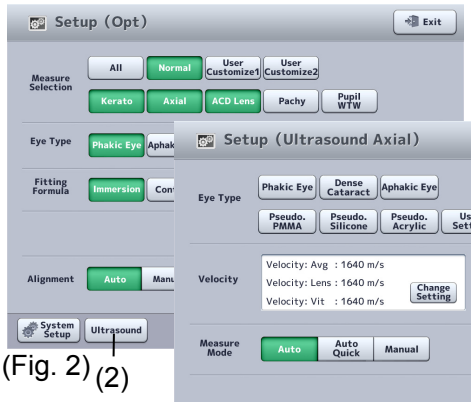
The brightness of the monitor can be adjusted according to illumination in the examination room. (Refer to “3.9.1 General.”)

3.2.4 Switching between optical (OPT) mode and ultrasound (US) mode

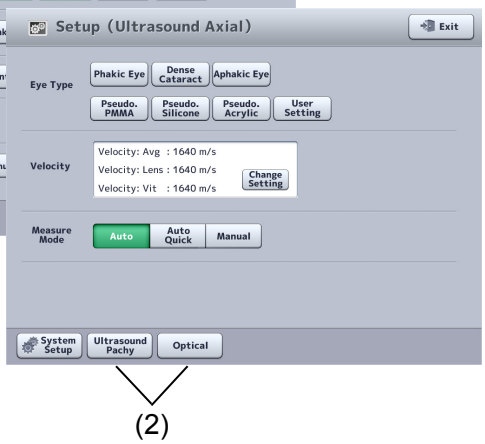
Touching the “Setup” button (1) on each screen displays the setup screen (Fig. 2) (Fig. 3). Touching any of the mode buttons (2) opens the measurement screen corresponding to the selected measurement mode.
Data obtained on this screen is retained after switching between the ultrasound (US) mode and the optical (OPT) mode.



(Fig. 1)



(Fig. 2)



(Fig. 3)

3.2.5 Entering the patient data

Note

- ***If the patient information and measurement data already exists, make sure that both the new patient information and existing measurement data belong to the same patient before replacing the existing patient information with the new data.***
- ***The patient’s ID can be entered only when the patient information entry screen is displayed.***
- ***Only the first 14 digits of the ID number are displayed in the patient information field. Check that the ID number is correct on the patient information entry screen.***
- ***The network support system “TOMEY Link” (optional) is required to use the patient information query function. “DATA Transfer” provided with the Machine is not available for query of the patient data.***
- ***For details on the TOMEY Link Server settings, refer to the TOMEY Link instruction manual.***
- ***Appropriate connection settings are required for connection with TOMEY Link. Refer to "3.9.4 d) PC connection settings" to make settings.***
- ***Once examination data is output (printed, exported or saved), the patient ID cannot be changed.***

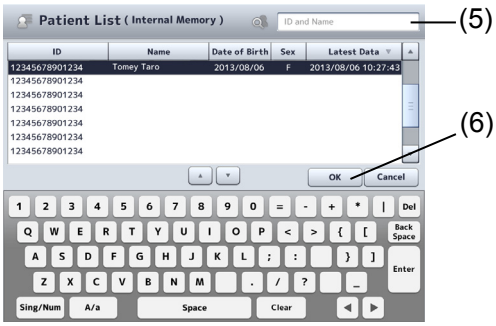
1) Touch the “ID" button (1) to open the Patient Information screen (Fig. 2).

(Fig. 1)

(Fig. 2)

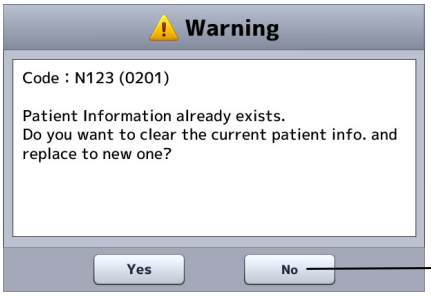
2) Enter the patient information using an external ID input device such as a barcode reader or the software keyboard (2) shown on the screen. After the patient ID is entered, touch the “Tomey Link Inquiry” button (3). The patient information is retrieved via Tomey Link and the result appears. When “Auto Inquiry” is set to ON, retrieved via TOMEY Link starts automatically when the ID is entered.
Touch the "Internal Memory Patient Search" button (4) to display the patient list (Fig. 3) saved in the memory. Search can be performed in the internal memory of the instrument or the connected external memory. The memory subject to search can be set according to “3.9.4 c) Media options / Data output format.”

3) Use the search function (5) in the Patient List screen (Fig. 3) to search IDs and patient names in the internal memory.
Select the desired patient and touch the "OK" button to update the patient information.



(Fig. 3)

4) After the patient information is entered, touch the "OK" button (7) to apply the entered data and return to the previous screen (Fig. 1). If an ID number is entered while the patient information and measurement data already exist, the confirmation screen (Fig 4) appears.



(Fig. 4)

5) Touch the “No” button (8) on the confirmation screen (Fig. 4) or the “No” button on the Patient Information screen (Fig. 2) to ignore the entered data and return to the previous screen (Fig. 1).

Entry of the patient ID from an external ID input device (barcode reader etc.) is accepted on the following screens.

- Patient Information screen
- Each measurement screen or view screen

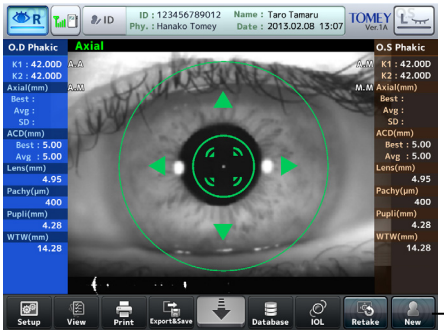
  Re-entry of the patient ID is not accepted after the examination data is output.

3.2.6 Clear all measurement data (preparation for measuring a new patient)

Note

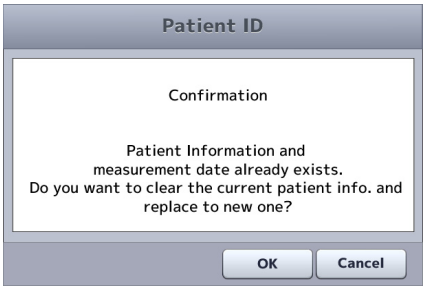
■ ***The deleted measurement data cannot be restored. Carefully check the data before deleting it.***

■ ***Be sure to touch the “New” button to delete all the measurement data for the previous patient before measuring another patient. If the measurement data of the next patient is captured without touching the “New” button, the patient information does not match the measurement data.***



(Fig. 1)

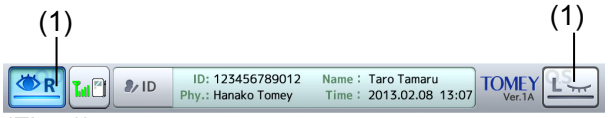
1) When the “New” button (1) is touched for approximately 1 second and a beep sounds, the patient information (ID, name, and sex) and measurement data is all deleted and the measurement screen appears.
The patient’s eye selection screen (Fig. 2) appears in any of the ultrasound modes.



(Fig. 2)

2) Select an eye and start new measurements.

3.2.7 Selecting an eye



(Fig. 1)

Touch either eye selection button (1) to select “R (right)” or “L (left)."

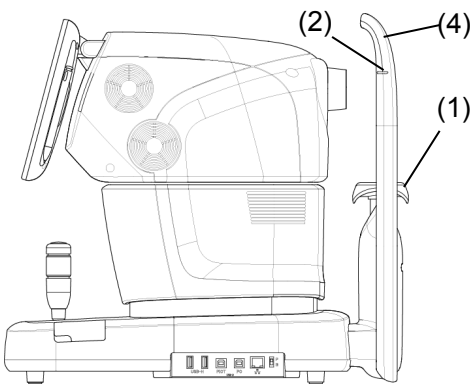
3.2.8 Patient's eye height adjustment

- ***When moving the measuring head and/or chin rest of the instrument, pay attention to the position of the patient's face, hands, and fingers. The patient may be injured by the moving section of the instrument.***
- ***The chin rest paper is provided to keep the chin rest clean. Use this paper for the chin rest as well as the patient to use this instrument comfortably.***
- ***Peel off the top sheet of chin paper and clean the forehead pad with a clean cloth before measuring the next patient. Clean the forehead pad with a cloth dampened with alcohol as needed.***

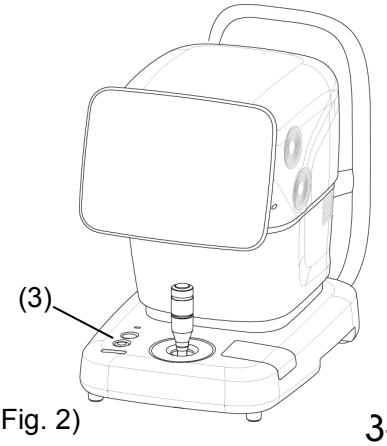
1) Have the patient place their face on the chin rest (1). Adjust the chin rest height so that the height of the corner of the eye is aligned with the eye level mark (2).

2) Press the chin rest button (3) at the front of the main unit (Fig. 2) to move the chin rest up and down.

3) When the patient's eye height is adjusted, lightly push the patient's forehead against the forehead pad (4) to secure the patient's position.



(Fig. 1)



(Fig. 2)

3.3 Optical measurement mode

Refer to “3.2.4 Switching between optical (OPT) mode and ultrasound (US) mode” for the method to switch to optical measurement mode.

Note

■ ***Calibration may be conducted automatically in optical measurement mode in order to smoothly perform measurement.No operation is available during calibration.Restart the operation after the message “Calibrating…” displayed during calibration disappears.***

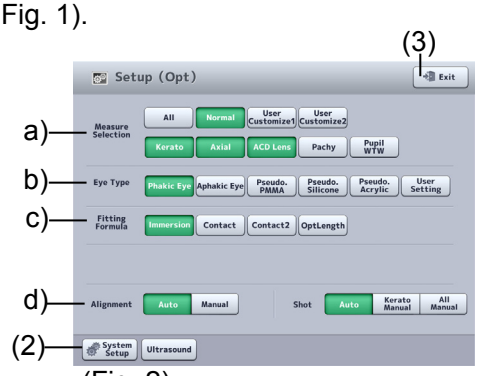
3.3.1 Setting measurement conditions

Note

■ ***Settings made on the Setup (OPT) screen are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.***

Touch the "Setup" button (1) at the lower left of the screen to open the Setup (OPT) screen (Fig. 2).
Settings made on the Setup (OPT) screen are effective for only one measurement. The settings will return to the status set on the System Setup (2) screen when one measurement is completed. Refer to “3.9 System Setup” for the “System Setup" button (2).
Touch the “Exit” button (2) after setting is completed to apply selected contents and return to the measurement screen (Fig. 1).

(Fig. 1)



(Fig. 2)

a) Selecting measurement items

The following 5 items can be measured simultaneously in optical measurement mode.

- **Axial length**
- **Pupil/corneal diameter**
- **Kerato**
- **Anterior chamber depth, lens**
- **Corneal thickness**

Select the item to be measured.
Touch the “All” button to select all items. Touch any of the “Standard," “Customize 1,” and “Customize 2” buttons to select the measurement items preset in the system setup. (Refer to “3.9.2 c) Settings for various measurements.”)

b) Selecting inspection eye

Select the inspection eye from the following 6 options.

- Phakic eye
  Select this in the case of phakic eyes.
- Aphakic eye
  Select this in the case of aphakic eyes.
- IOL eye (PMMA)
  Select this when a PMMA IOL is implanted.
- IOL eye (silicon)
  Select this when a silicon IOL is implanted.
- IOL eye (acryl)
  Select this when an acrylic IOL is implanted.
- User settings
  Select this when registering optional materials for IOL eyes.

c) Selecting fitting formula

Select the fitting formula from four options as listed below.

● Immersion ● Contact ● Contact 2 ● Optical length

d) Setting Auto Alignment and Auto Measurement

Note ■ ***Use Manual mode only when measurement must be performed even though the sight-fixing condition is unstable. Correct alignment is difficult in Manual mode and measurement errors easily occur.***

Follow the procedures below to make settings for Auto Alignment and Auto Measurement.

3.3.2 Alignment

CAUTION ■ ***Do not allow any person to place their hands or fingers in the clearance under the measuring head or the section under the chin rest. Their hands or fingers may be caught and injured.***

Note ■ ***Measurement results may be affected if the patient's eyelid and/or eyelashes cover the automatic alignment ring during measurement.***

■ ***Ask the patient to open their eyes wide or have the physician lightly hold the patient's upper eyelid with their fingers.***

■ ***Auto Alignment may not be effective when the patient blinks frequently during measurement. Ask the patient to stop blinking during measurement.***

■ ***Ask the patient to look into the fixation light in the measurement window. If the patient looks in a different direction or moves, the measurement may not be conducted correctly.***

■ ***This instrument is designed to perform measurement in Auto mode to ensure higher accuracy through standard operation. However, Auto Alignment may not be particularly effective when insufficient light is reflected due to deformation or inflammation of the cornea. In this case, conduct measurement manually.***

■ ***The reflection in the center of the cornea may not be clearly viewed when any deformation and/or inflammation of the cornea is severe. In this case, an error may occur even in Manual mode.***

a) Auto Alignment setting

Refer to “3.3.1 Setting measurement conditions.”

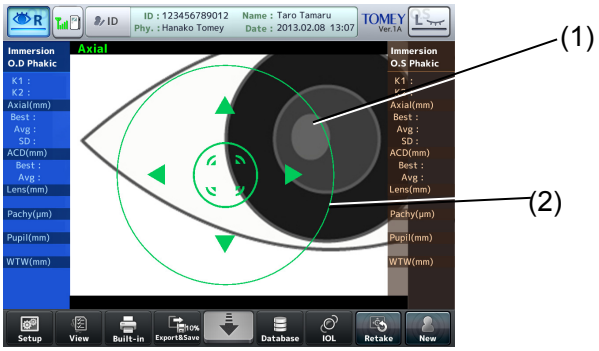
b) Positioning by Touch Alignment

Note

■ ***When moving an element up, down, left and right using Touch Alignment, touch the panel and release your finger immediately. Do not press the panel continuously.***

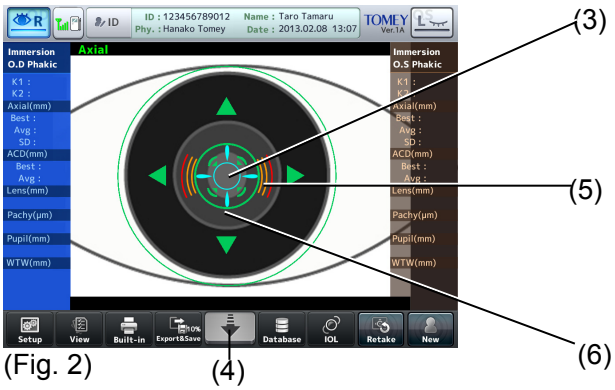
1) Use Touch Alignment or the joystick to position the patient's eye on the screen.

2) Lightly touch the center of the cornea (1) on the screen. The measuring head moves so that the patient's eye is positioned in the center of the screen. When the center of the cornea (1) enters the alignment ring (2) with Auto Alignment turned on, focusing in the X and Z axes automatically starts.



(Fig. 1)

3) Perform alignment in the Y axis. While pressing the center of the screen (3), the measuring head advances towards the patient. Touch the measuring head retract button (4) to retract the measuring head towards the physician.



(Fig. 2)

4) When the focus indicator (5) appears while Auto Alignment is activated, focusing in the Y axis starts automatically. When alignment conditions are optimal, the alignment OK mark (6) is displayed.

c) Positioning by the joystick

Note

- ***This instrument is designed to perform measurement in Auto mode to ensure higher accuracy through standard operation. However, Auto Alignment may not be particularly effective when insufficient light is reflected due to deformation or inflammation of the cornea. In this case, conduct measurement manually.***
- ***The reflection in the center of the cornea may not be clearly viewed when any deformation and/or inflammation of the cornea is severe. In this case, an error may occur even in Manual mode.***

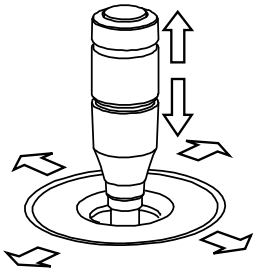
There are two types of operations - rough operation for roughly positioning the measuring head and fine operation for finely adjusting the position of the measuring head.

[Rough operation]

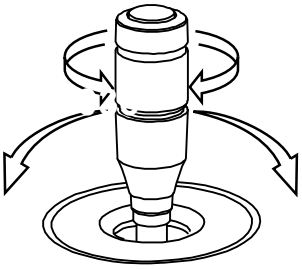
Moving the joystick moves the measuring head back, forth, left, and right. When the up/down ring is slid up and down, the head moves up and down. (Fig. 1)

[Fine operation]

Tilting the joystick moves the measuring head in the tilting direction. Turn the up/down ring to move the head up and down. (Fig. 2)



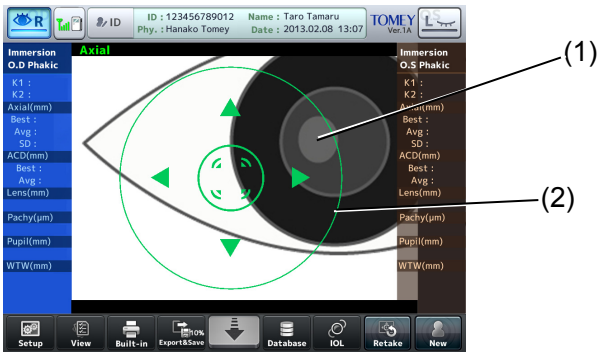
(Fig. 1)



(Fig. 2)

Clockwise
The head rises.
Counterclockwise
The head lowers.

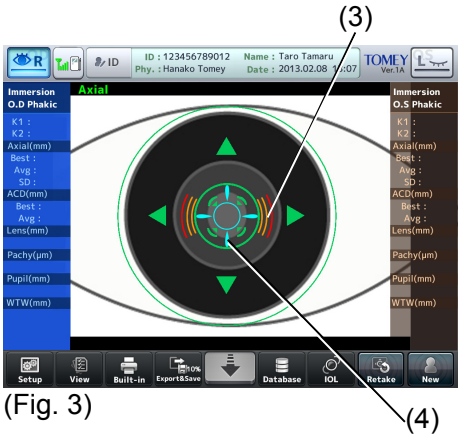
1) Operate the joystick so the center of the pupil (1) enters the target ring (2).



(Fig. 2)

2) Move the joystick back and forth to move the measuring head so that the focus indicator (3) on the screen becomes small.
When the focus indicator (3) is shown horizontally, the measuring head is too far from the eye; when the focus indicator is shown vertically, the measuring head is too close to the eye. When the focus indicator (3) does not appear, align the focus with the iris.

3) When alignment conditions are optimal, the alignment OK mark (4) is displayed.



(Fig. 3)

3.3.3 Measurement

Note

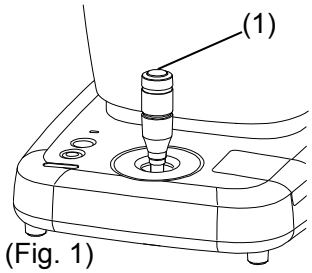
- ***Measure and display the selected measurement item only. Refer to "3.3.1 Setting measurement conditions" for selection method.***
- ***Be sure to touch the "New" button to delete all the measurement data of the previous patient before measuring another patient. If new measurement is started without deleting the previous data, the measurement data of the previous patient may be included.***
- ***The deleted data cannot be restored. Carefully check the data before deleting it.***
- ***If the measurement value is output when measuring axial length, be sure to check waveforms, images, and reliability on the view screen.***
- ***If any problem is found on waveforms when measuring axial length, be sure to perform other examinations.***
- ***When the difference between left and right in the axial length measurement is more than 1 mm, be sure to perform other examinations.***
- ***When there are multiple higher peaks detected in the axial length measurement, the retinal pigment epithelium may not have been detected correctly. Check that the retinal pigment epithelium has been detected on the caliper screen.***
- ***As for measurement of the radius of corneal curvature, if the difference between measurement values on the left and right eyes is large or any problem is found on the cornea during the preliminary examination, be sure to check the image of the measurement ring pattern on the view screen.***
- ***If reliability of measurement values is low when measuring the radius of corneal curvature, check the measurement ring pattern. If any problem is found, be sure to perform other examinations.***

■ ***Do not determine application of LASIK based only on measurements by this instrument and be sure to refer to other examinations.***

■ ***Do not determine IOL types or ICL sizes based only on measurements by this instrument and be sure to refer to other examinations.***

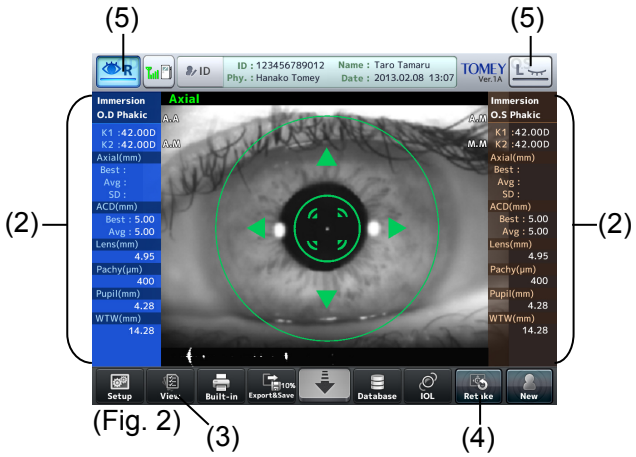
1) Adjust the patient's eye height and ask the patient to look at the red lamp in the measurement window. (Refer to "3.2.8 Patient's eye height adjustment.") When capturing an image immediately after having the patient blink and open their eye widely, partial missing in the color code map due to breakage of the tear film or insufficient opening of the eye can be reduced.

2) Perform alignment. (Refer to "3.3.2 Alignment.")
If measurement is in auto mode, measurement starts automatically after alignment is complete. If measurement is in manual mode, press the measurement button (1) on the joystick (Fig. 2) after alignment is complete to start measurement.
The number of times the data is taken per measurement can be set in system setup. (Refer to "3.9 System setup.")



(Fig. 1)

3) When measurement has been completed, the measured data (2) appears. A representative value appears here. Press the "View" button (3) to look at all data taken for each measurement item.



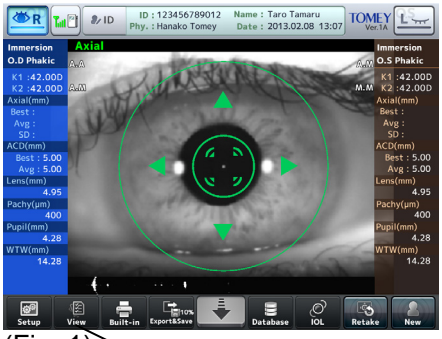
(Fig. 2)

4) Touch the "Retake" button (4) for approximately 1 second until a beep sounds to delete the last measurement data and measure the same eye again.

5) Touch the eye display button (5) to change the eye to be measured. The measuring head moves toward the selected eye.

3.3.4 Browsing and editing axial length measurement

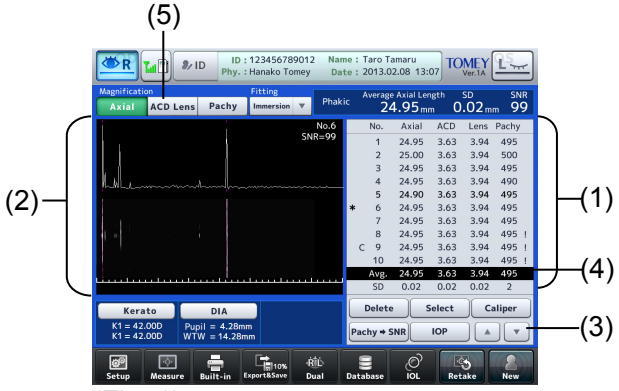
Touch the "View" button (1) at the lower left of the measurement screen (Fig. 1) to open the axial length view screen (Fig. 2).
Touch the “Measure" button (2) on the view screen (Fig. 2) to return to the measurement screen (Fig. 1).



(Fig. 1) (1)

(Fig. 2) (2)

a) Browsing measurement values



(Fig. 1)

1) Measurement values (1) and scanned image / waveform (2) are displayed with the average data selected when the screen appears. Touch the data selection buttons (3) to move the cursor (4).
The following marks are assigned to the measurement data.

*	:	Data used for calculating IOL power
!	:	Data with low reliability
C	:	Callipered data

2) Touch the display area selection button (5) to show the image at magnification and position where the selected section can be checked.

Axial length /ACD (anterior chamber depth), Lens / Corneal thickness

b) Deleting and recovering measurement values

(Fig. 1)

1) Touch the “Delete” button (1) to delete the data selected with the cursor and the data color changes to gray. The data deleted here is excluded from the integral calculus value and average.

2) To recover the deleted data, move the cursor to the data. Touch the “Recall” button (2) to cancel deletion.

3) When returning to the measurement screen after deleting the data, measurement can be performed and data can be loaded for the number of deleted datasets.

c) Caliper function

Note

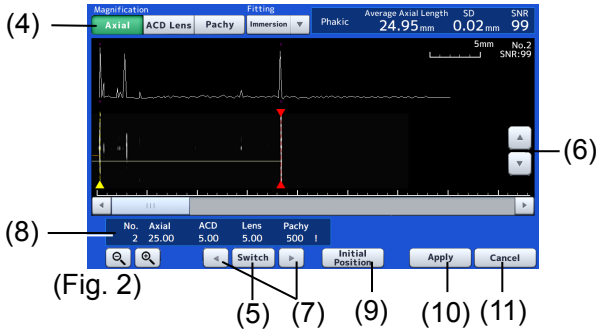
■ ***Values measured and displayed using the caliper function are rough estimates and may differ from the actual measurement result.***

This function is used to measure the distance at an arbitrary section of the measurement waveform. 4 dotted caliper lines appear, and the distance between these 2 points is displayed. The selected and active caliper line is displayed in red and the other lines are displayed in yellow.

(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data which is to be measured.

2) Touch the "Caliper" button (3) to open the caliper screen (Fig. 2).



(Fig. 2)

3) Select the display area (4).The following caliper lines will be displayed.
   Axial length : Front of cornea, retina
   Anterior chamber dept / lens : Front of cornea, front of crystal lens, back of crystal lens
   Corneal thickness : Front of cornea, back of cornea

4) Touch the “Switch” button (5) of the active caliper line to select the caliper line to be changed. The selected caliper line is displayed in red but the other lines are displayed in yellow.

5) Use the selection buttons (6) on the right of the scanned image to change the waveform to be displayed. Select the position where the peak of the waveform to be callipered can be best confirmed.

6) Touch the caliper line movement buttons (7) to change the caliper line position. The changed measurement data is displayed in the edit data display field (8) along with the movement of the caliper line.
The distance between the cornea caliper line and the retina caliper line is displayed in Axial length, the distance between the cornea caliper line and the caliper line for the front of the crystal lens is displayed in ACD, and the distance between the caliper line for the front of the crystal lens and the caliper line for the back of the crystal lens is displayed in Lens.

7) If you have edited it mistakenly, touch the “Initial Position” button (9) to cancel the changes made, and the caliper line will return to the position before the editing.

8) When you touch the “Apply” button (10), the changes made are applied, the measurement data is overwritten with the edited measurement data, and the caliper screen is closed. Touching the “Cancel” button (11) will discard the changes made, and the caliper screen is closed.

d) Selecting specific measurement data to be used for calculating IOL power

The average value is normally adopted for the measurement data to be used in calculating the IOL power, but specific measurement data can also be selected.

(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the measurement data which is to be used in calculating the IOL power. To use the average value in IOL power calculation, move the selection cursor (2) to the average data.

2) When the “Select” button (3) is touched, it is selected as the data to be used in calculating the IOL power, and a “*” appears on the left of the data.

3.3.5 Browsing corneal thickness measurement value and correcting intraocular pressure

(Fig. 1)

1) Touch the ‘‘Pachy -> SNR’’ button (1) to switch the measurement data list between Pachy and SNR.

2) Touch the “IOP" button (2) to open the intraocular pressure correction screen (Fig. 2). When a measurement has already been completed at this point, the measured value is displayed in the CCT field (3).

(Fig. 2)

3) The input fields of parameter 1 (4) and parameter 2 (5) for the intraocular pressure correction formula become active when touched, and the keypad appears. Also, when a formula selection button (6) is touched, the parameters already set are displayed in the intraocular pressure correction formula.
[Input range]
■ Parameter 1 : 0 - 1500
■ Parameter 2 : 0.0000～1.0000

4) Enter the intraocular pressure data. The keypad appears when the entry field (7) is touched.
[Input range]
■ Intraocular pressure data : 1 - 60.0 (mmHg)
: 1.33 - 79.99 (hPa)
The unit for display can be changed according to “3.9.2c) Settings for various measurements.”

5) Touch the “Back” button (8) to close the intraocular pressure correction screen (Fig. 2) and return to the previous screen.

3.3.6 Browsing and editing keratometer measurement

a) Browsing measurement values

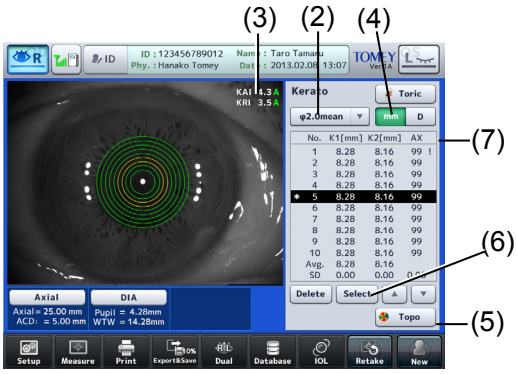
Note

■ ***The corneal irregular astigmatism display function is a simple measurement using keratometer measurement. This function does not detect all cases of corneal irregular astigmatism. Measurement itself or correct measurement may not be performed for some corneal shapes such as if there is a partial problem on the corneal shape.***

■ ***Because the corneal irregular astigmatism display function requires more information than keratometer measurement, corneal irregular astigmatism may not be measured even though keratometer measurement can be performed.***

(Fig. 1)

1) Touch the "Kerato" button (1) on each view screen to open the kerato view screen (Fig. 2).
The default view for measurement position is determined by the fitting formula used in the measurement.
Immersion shows φ2.5 mm. Other fitting fomula shows φ3.0 mm.



(Fig. 2)

2) Touch the measurement position display button (2) to select the section to be displayed.
ϕ2.0mean / ϕ2.5 / ϕ3.0
ϕ2.0mean displays only mean values.
When measurement position φ3.0 is selected, the indexes of KAI and KRI (3) measured by keratometer measurement are displayed. KAI represents asymmetry of the corneal shape and KRI represents regularity (irregularity) of the corneal shape. A larger value for this index means irregular astigmatism.
Possibility of corneal irregular astigmatism is shown as levels A, B, and C.
Level A : Improbable to be corneal irregular astigmatism such as keratoconus
Level B : Slightly probable to be corneal irregular astigmatism such as keratoconus
Level C : Highly probable to be corneal irregular astigmatism such as keratoconus
Thresholds for levels A, B, and C are as shown below.

	A (Green)	B (Yellow)	C (Red)
KAI	0.0 ~ 23.4	23.5 ~ 29.0	29.1 ~
KRI	0.0 ~ 4.4	4.5 ~ 5.2	5.3 ~

(Refer to “4.5 Corneal irregular astigmatism display function.”)

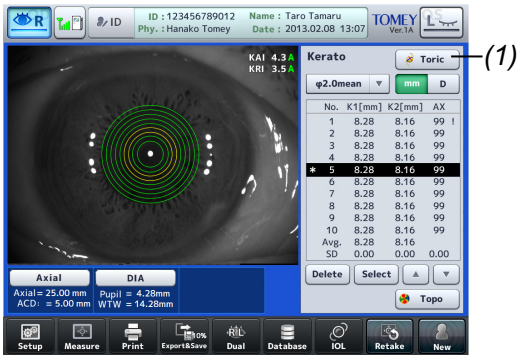
3) Touch the “mm/D” button (4) to change the unit for display.

4) “*” is shown for the data used for IOL power calculation. To select the desired data, move the cursor to the desired data using the cursor button (4) and then touch the “Select" button (6). The specified data is selected for IOL power calculation.
If the measurement value lacks reliability because the patient’s eyelid and/or eyelashes interfere with the measuring point etc., “!” appears (7).

b) Deleting and recovering measurement values

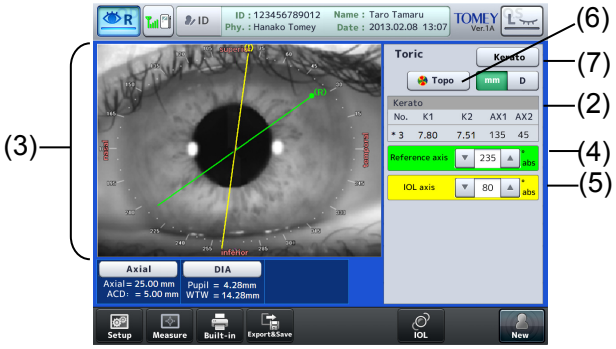
Refer to “3.3.4 b) Deleting and recovering measurement values.”

c) Auxiliary function for toric lens



(Fig. 1)

1) Touch the ‘‘Toric’’ button (1) on the kerato view screen to open the auxiliary function screen for eyes with a toric lens (Fig. 2).



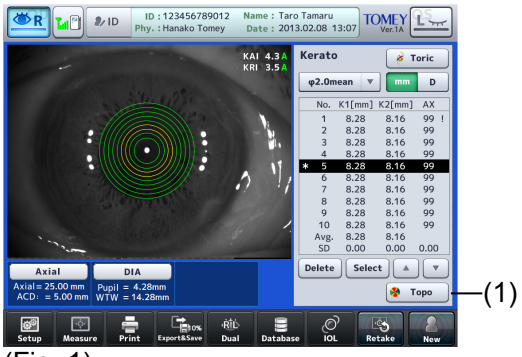
(Fig. 2)

2) Measurement values (2) selected on the kerato view screen appear. In addition, the axis angle line for the characteristic point (green) and the IOL axis angle line (yellow) are shown on the camera image (3).

3) Enter an angle to the Reference axis (green) (4) and IOL axis (yellow) (5) fields, and change positions of the corresponding lines on the camera image.

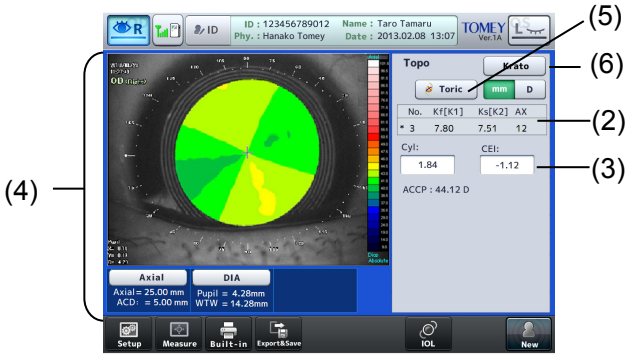
4) Touch the "Topo" button (6) to display the TOPO view screen.Touch the “Kerato” button (7) to return to the kerato review screen (Fig. 1).

d) Topography function



(Fig. 1)

1) Touch the “Topo” button (1) on the Topo view screen to open the view screen (Fig. 2).



(Fig. 2)

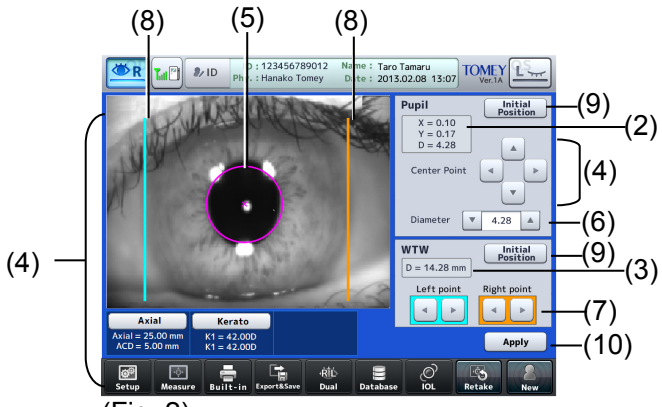
2) Measurement values (2) selected on the kerato view screen, and the astigmatism axis angle and corneal eccentricity factor (3) are shown. The single map and scale are shown in the image display field (4).

3) Touch the “Kerato” button (7) to return to the kerato review screen (Fig. 1).

3.3.7 Browsing and editing pupil diameter and corneal diameter measurement values

(Fig. 1)

1) Touch the "DIA" button (1) on each view screen to open the pupil/corneal diameter view screen (Fig. 2).



(Fig. 2)

2) Measured pupil diameter (2) and corneal diameter (3) are shown. The fitting circle and center point for analyzing the pupil diameter, and measurement lines for analyzing the corneal diameter are shown on the CCD image.

3) Touch any of the Center Point buttons (4). The circle (5) moves on the image, and the X and Y values of the measurement (2) change accordingly. Touch the circle (5) on the image to move the center point of the circle to the touched point.

4) Touch the up/down arrow buttons for the diameter editing tool (6) to change the diameter of the circle (5).

5) Touch the Left point and Right point arrow buttons of the corneal diameter editing tool (7). The measurement lines (8) on the image move accordingly and the corneal diameter value (3) changes.

6) Touch the “Initial Position” button (9) to reset each value to the status when the pupil/corneal diameter view screen opened.

7) Touch the “Apply” button (10) to define the changes. Nothing can be returned to the original positions after the “Apply” button is touched.

3.4 Ultrasound axial length measurement mode

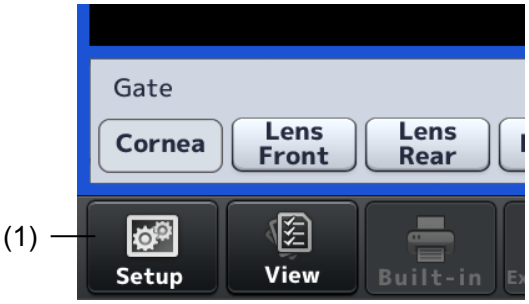
Refer to “3.2.4 Switching between optical (OPT) mode and ultrasound (US) mode” for the method to switch to ultrasound measurement mode.

3.4.1 Setting measurement conditions

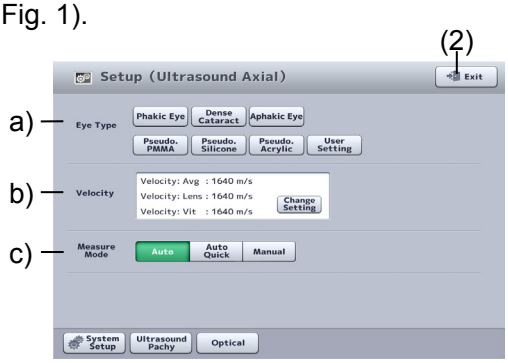
Note

■ ***Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.***

Touch the "Setup" button (1) to display the Setup (Ultrasound Axial) screen (Fig. 2). Set items related to operation conditions.
Touch the “Exit” button (2) after setting is completed to apply selected contents and return to the measurement screen (Fig. 1).



(Fig. 1)



(Fig. 2)

a) Selecting inspection eye

Select the inspection eye from the following 7 options.

- Phakic eye
  Select this for a normal eye or when the crystalline lens nucleus is comparatively soft, such as an eye in the initial stages of cataracts.

- Dense cataract eye
  Select this when the crystalline lens nucleus of the inspection eye is comparatively hard, such as an eye with dense cataracts, and it is difficult to take measurements in the mode used for a phakic eye with an echo reflected in the crystal lens.

- Aphakic eye
  Select this in the case of aphakic eyes.

- IOL eye (PMMA)
  Select this when a PMMA IOL is implanted.

- IOL eye (silicon)
  Select this when a silicon IOL is implanted.

● IOL eye (acryl)
Select this when an acrylic IOL is implanted.

● User Setting
Select this when registering optional materials for IOL eyes.
Register the settings on the converted acoustic velocity setting screen.
(Refer to ‘‘Setting converted acoustic velocity.’’)

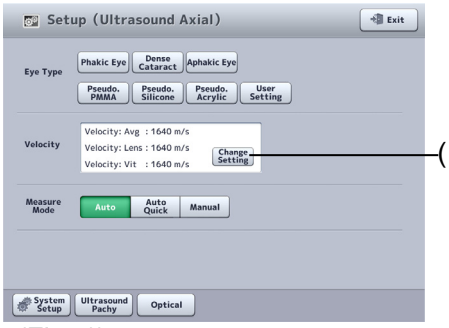
“Anterior chamber depth” and “lens” are not measured for an aphakic eye and “lens” is not measured for an IOL eye.
The instrument may not recognize waveforms on the back of the crystal lens due to multiechoes in the crystal lens in an eye with dense cataracts.

Inspection eye	Axial length	ACD (anterior chamber depth)	Lens
Phakic eye (Average acoustic velocity, divisional acoustic velocity)	○	○	○
Dense cataract eye	○	○	△
Aphakic eye	○	※	※
IOL eye (All materials)	○	○	※

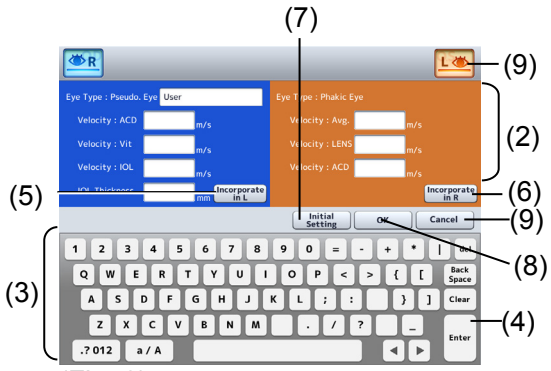
○: Measurements are displayed.
△: Measurements may not be displayed.
※: Measurements are not displayed

b) Setting converted acoustic velocity

Touch the ‘‘Change Setting’’ button (1) to open the setting change screen (Fig. 2).



(Fig. 1)



(Fig. 2)

1) Entry boxes (2) for the acoustic velocities required for the inspection eye currently selected appear. Enter the converted sonic velocity using the software keyboard (3).

2) After entry, touch the “Enter” key (4) to move to the next entry box. Also, by touching the “Incorporate in L” button (5) or the “Incorporate in R” button (6), the data entered will be applied to the other eye.

3) Touch the “Initial Setting” button (7) to enter the initial settings.

4) Touch the "OK" button (8) to apply the entry and return to the Setup (Ultrasound Axial) screen. Touch the "Cancel" button (9) to discard the entry and return to the Setup (Ultrasound Axial) screen with the previous sonic velocity still set.

(Initial setting and setting range of converted acoustic velocity)

● Phakic eye

Average acoustic velocity for axial length		: 1,550m/s, 1,500 - 1,600m/s
Crystal lens acoustic velocity		: 1,641m/s, 1,540 - 1,740m/s
Anterior chamber depth acoustic velocity		: 1,532 m/s, 1,430 - 1,630m/s
Vitreous acoustic velocity (divisional velocity only)		: 1,532 m/s, 800 - 2,000 m/s

● Dense cataract eye

Average acoustic velocity for axial length		: 1,548m/s, 1,500 - 1,600m/s
Crystal lens acoustic velocity		: 1,629m/s, 1,540 - 1,740m/s
Anterior chamber depth acoustic velocity		: 1,532 m/s, 1,430 - 1,630m/s

● Aphakic eye

Average acoustic velocity for axial length		: 1,532 m/s, 1,430 - 1,630m/s

● IOL eye

Implanted lens acoustic velocity	(Acryl)	: 2,200m/s, 800 - 3,000m/s
	(Silicone)	: 1,049m/s, 800 - 3,000m/s
	(PMMA)	: 2,718m/s, 800 - 3,000m/s
Anterior chamber depth acoustic velocity		: 1,532 m/s, 1,460 - 1,630m/s
Vitreous acoustic velocity		: 1,532 m/s, 800 - 2,000 m/s
IOL thickness	(Acryl)	: 0.80 mm, 0.10 - 4.00 mm
	(Silicone)	: 1.00 mm, 0.10 - 4.00 mm
	(PMMA)	: 0.80 mm, 0.10 - 4.00 mm

c) Measurement mode

Set the measurement mode.

● Auto
Select this for normal measurements.

● Auto quick
Select this when measurement is difficult.

● Manual
Select this when measurement is difficult in Auto and Auto quick modes.

d) Setting contact/immersion mode

Complete the settings for contact mode and immersion mode referring to "3.9.2 Measurement setting."

3.4.2 Measurement

See the user's manual of the AL-4000 for the actual measurement procedure. This section describes the operations that can be performed with this instrument during measurement.

Note

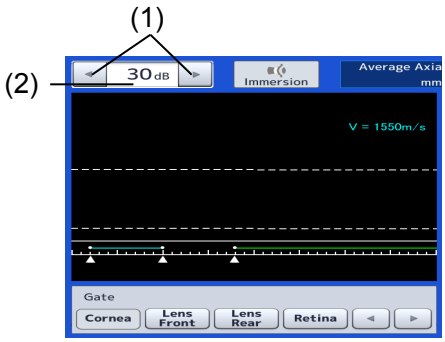
- ***The converted acoustic velocity directly affects the measurement data. Check that the desired value is set before starting measurement.***
- ***Check the settings in contact mode and immersion mode before starting measurement. In immersion mode, apply an ultrasound media such as cornea protective agent so that the clearance between the cornea and the contact section of the biometry probe is approximately 2.0 – 5.0 mm.***
- ***The automatic measurement function is an auxiliary function to take measurements more easily. This is not a function for making actual clinical judgments. The physician must examine the measurement result before using it.***
- ***Be sure to touch the "New" button to delete all the measurement data of the previous patient before measuring another patient. If new measurement is started without deleting the previous data, the measurement data of the previous patient may be included.***

a) Setting gain

Note

- ***Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.***

Adjust the waveform height according to the gain settings. The gain and the waveform height increases as the gain value increases.



(Fig. 1)

Touch the gain adjustment buttons (1) to change the gain. The setting continues to change while the button is held. The set value is displayed in the gain display (2).

b) Setting gate cursor

Note

- ***Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.***

(Fig. 1)

1) Select a gate cursor to be adjusted by touching the gate selection buttons (1). The selected and active cursor is displayed in red but the other cursors are displayed in white.

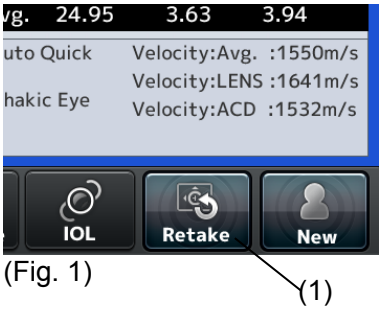
2) Touch the gate cursor movement buttons (2) to set the active gate cursor position.

c) Re-measurement of the same patient

Note

■ ***The deleted data cannot be restored. Carefully check the data before deleting it.***

Retain the patient information and delete only the measurement data for each eye. Delete all data referring to “3.2.6 Clear all measurement data (preparation for measuring a new patient)” when the patient is changed.

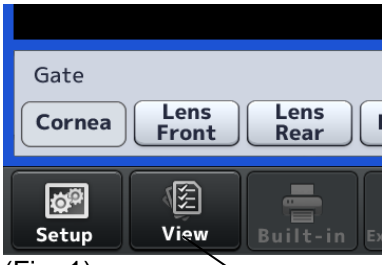


(Fig. 1)

Touch the “Retake” button (1) for approximately 1 second until a beep sounds to delete the data. It retains the patient information and the measurement data of the eye other than the inspected eye being displayed.

3.4.3 Checking waveforms after measurement

a) Displaying waveform of arbitrary measurement data



(Fig. 1)

1) When all necessary measurement data is captured or when the “View” button (1) is touched, the edit screen (Fig. 2) opens.

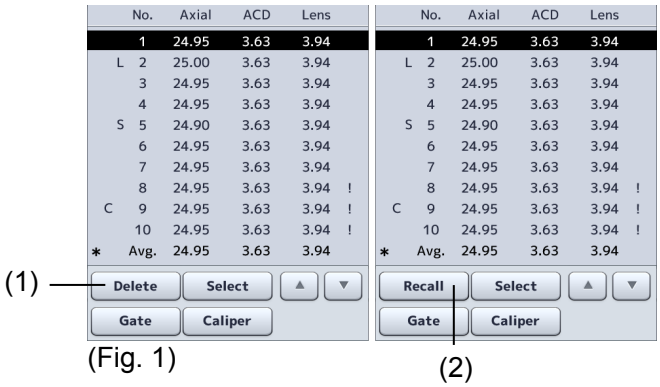
(Fig. 2)

2) The waveform measured at the selected cursor (2) is displayed in the waveform display field (3). Touch the selection cursor movement buttons (4) to move the selection cursor (2) up or down.

The following marks are assigned to the measurement data.

∗	:	Data used for calculating IOL power
!	:	Data with low reliability
L	:	Longest axial length
S	:	Shortest axial length
C	:	Callipered data

b) Deleting and recovering measurement values

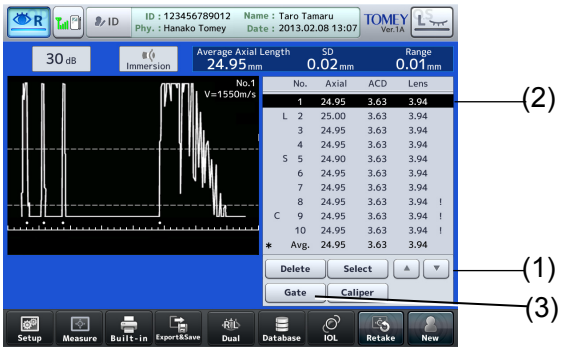


(Fig. 1)

1) Touch the “Delete” button (1) to delete the data selected with the cursor and the data color changes to gray. The data deleted here is excluded from the average.

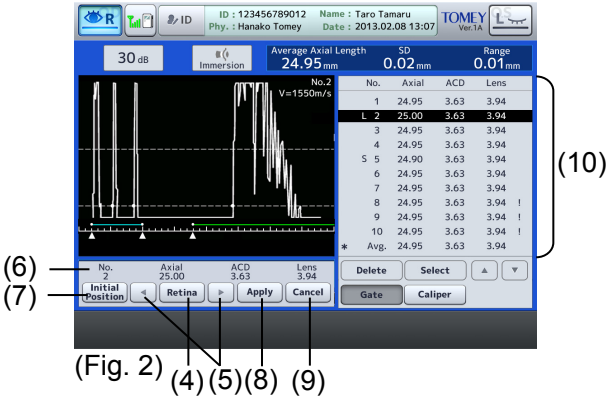
2) To recover the deleted data, move the cursor to the data. Touch the “Recall” button (2) to cancel deletion.
However, once the screen returns to the measurement screen, the deleted data cannot be restored by the “Return” button even when the screen is switched to the edit screen again.

c) Gate change function



(Fig. 2)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data to be changed. Touch the “Gate” button (3) to open the gate change screen (Fig. 2).



(Fig. 2) (4) (5) (8) (9)

2) Touch the gate cursor selection buttons (4) to select the gate cursor to be changed. The selected and active gate cursor is displayed in red but the other cursors are displayed in white.

3) Touch the “gate cursor movement” buttons (5) to change the position of active gate cursor. The changed measurement data is displayed in the edit data display field (6) along with the movement of the gate cursor.

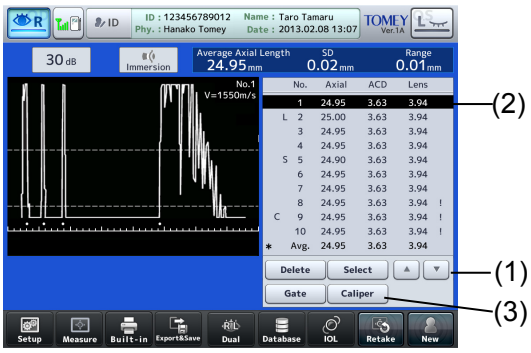
4) If you have edited it mistakenly, touch the “Initial Position” button (7) to cancel the changes made, and the gate cursor will return to the position before the editing.

5) When you touch the “Apply” button (8), the changes made are applied, the measurement data displayed in the measurement data display field (10) is overwritten with the edited measurement data, and the gate change screen is closed. If the “Cancel” button (9) is touched, the changes made are discarded and the gate change screen is closed.

d) Caliper function

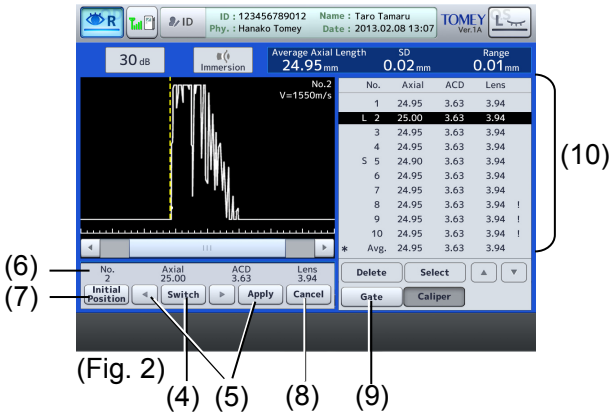
Note ■ ***Values measured and displayed using the caliper function are rough estimates and may differ from the actual measurement result.***

This function is used to measure the distance of the measurement waveform. Three dotted caliper lines (four lines in immersion mode) appear and the distance to the selected caliper line is displayed.



(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data to be measured. Touch the “Caliper” button (3) to open the caliper screen (Fig. 2).



(Fig. 2)

2) Touch the “Switch” button (4) of the active caliper line to select the caliper line to be changed. The selected caliper line is displayed in red but the other lines are displayed in yellow.

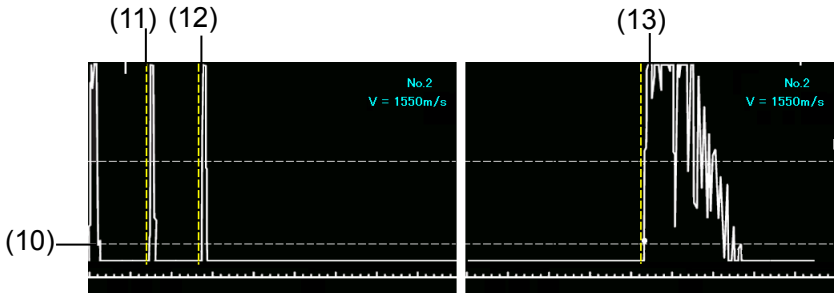
3) Touch the caliper line movement buttons (5) to change the active caliper line position. The changed measurement data is displayed in the edit data display field (6) along with the movement of the caliper line.

4) If you have edited it mistakenly, touch the “Initial Position” button (7) to cancel the changes made, and the caliper line will return to the position before the editing.

5) When you touch the “Apply” button (8), the changes made are applied, the measurement data displayed in the edit data display field (6) is overwritten with the measurement data specified by the cursor (2), and the caliper screen is closed. Touching the “Cancel” button (9) will discard the changes made, and the caliper screen is closed.

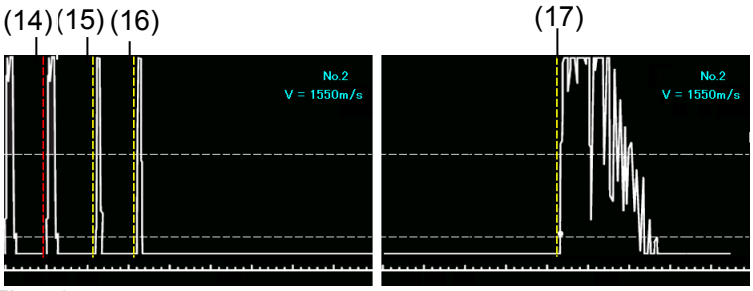
● In contact lens mode (Fig. 3)
The distance between the start line of the waveform (0 mm point) (10) and the retina caliper line (13) is shown in the axial length field, that between the start line of the waveform (10) and the caliper line for the front of the crystal lens (11) is shown in the ACD (anterior chamber depth) field, and that between the

caliper lines for the front of the crystal lens (11) and for the back of the crystal lens (12) is shown in the Lens field.



(Fig. 3)

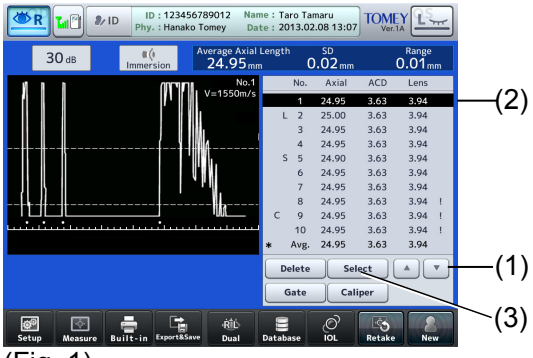
- In immersion mode (Fig. 4)
  The distance between the cornea caliper line (14) and the retina caliper line (17) is displayed in Axial length, the distance between the cornea caliper line (14) and the caliper line for the front of the crystal lens (15) is displayed in ACD, and the distance between the caliper line for the front of the crystal lens (15) and the caliper line for the back of the crystal lens (16) is displayed in Lens.



(Fig. 4)

e) Selecting specific measurement data to be used for calculating IOL power

The average value is normally adopted for the measurement data to be used in calculating the IOL power, but specific data can also be selected.



(Fig. 1)

1) Use the selection cursor movement buttons (1) to move the selection cursor (2) to the data which is to be used in calculating the IOL power. To use the average value in IOL power calculation, move the selection cursor (2) to the average data at the bottom.

2) When the “Select” button (3) is touched, it is selected as the data to be used in calculating the IOL power, and a “*” appears on the left of the data.

3.5 Ultrasound corneal thickness measurement mode

Refer to “3.2.4 Switching between optical (OPT) mode and ultrasound (US) mode” for the method to switch to ultrasound corneal thickness measurement mode.

3.5.1 Setting the data type to be displayed

Select the measurement data type to be displayed from the following three options.

- Latest : Displays the last measurement data taken.
- Minimum : Displays the minimum value of measurement data.
- Average : Displays the average of measurement data.

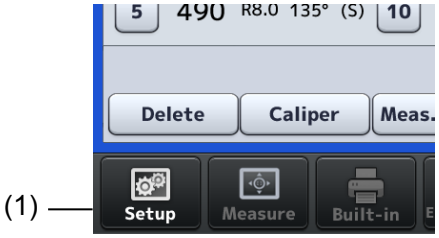
Make settings referring to “3.9.2 C) Settings for various measurements.”

3.5.2 Setting measurement conditions

Note

■ ***Settings made here are only effective for the eye currently selected. Settings cannot be made for both eyes simultaneously. Complete necessary settings for each eye.***

Touch the "Setup" button (1) to display the Setup (Ultrasound Pachy) screen (Fig. 2). Set items related to operation conditions. Touch the “Exit” button (2) after setting is completed to apply selected contents and return to the measurement screen (Fig. 1).



(Fig. 1)

(Fig. 2)

a) Measurement range

Select the measurement range from the following 3 options.

- 150 – 350 µm
- 300 – 1000 µm
- 900 – 1500 µm

b) Selecting measurement values to be displayed

Select measurement values to be displayed from the following 2 options.

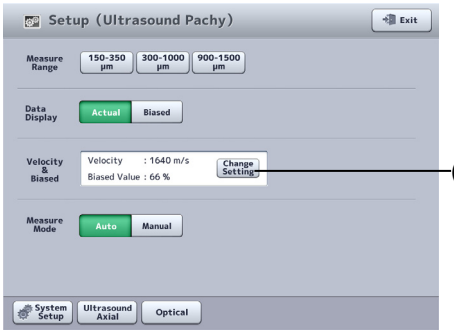
- Actual measurement
- Bias value

c) How to display converted acoustic velocity and bias values

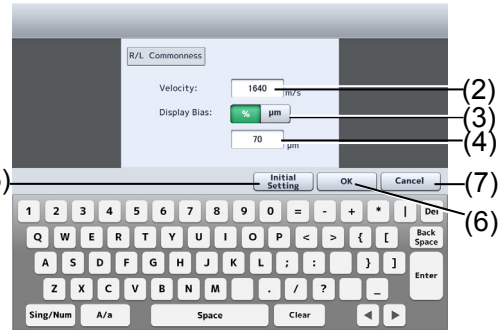
Select how to display the bias value from the following two options.

- Percentage bias: Converts the actual measurement using the preset bias rate (percentage) and displays the result.
- Plus/minus bias: Adds/subtracts the preset correction value to/from the actual measurement, and displays the result.

1) Touch the “Change Setting” button (1) on the Setup (Ultrasound Pachy) screen to display the screen for setting converted sonic velocity and bias value (Fig. 2).



(Fig. 1)



(Fig. 2)

2) When the converted sonic velocity entry field (2) is touched, it is activated. Enter the converted sonic velocity using the software keyboard. Initially, it is set to 1640 m/s.

   Input range of converted acoustic velocity: 1400 - 2000 m/s

3) Touch the "Display of Bias" button (3) to select the percentage bias (%) or plus/minus bias (µm).
   Using the software keyboard, enter the bias rate when percentage bias is selected, or the correction (4) when plus/minus bias is selected. Initially, the bias rate is set to 70 % and the correction is set to 0 µm.

   Input range of bias rate: 60 - 130%
   Input range of correction: -600 - +450µm

4) When a value is entered for one eye, the setting for the other eye is automatically changed. Touch the “Initial Setting” button (5) to enter the initial settings.

5) Touch the “OK” button (6) to apply the entered settings and close the setting change screen. Touch the “Cancel” button (7) to discard the entered settings and close the setting change screen.

d) Measurement mode

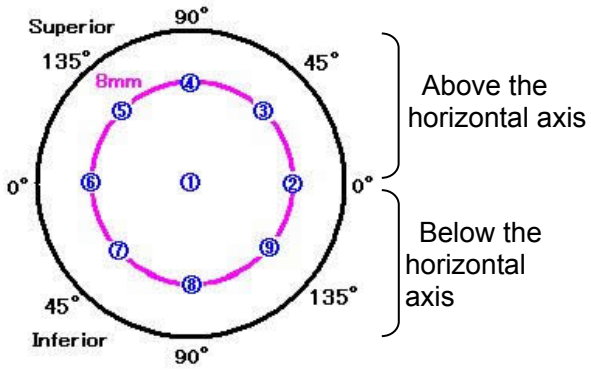
Set the measurement mode.

- Auto
- Manual

Select manual measurement when it is difficult to measure in Auto mode or when measurement values are captured while not performing a measurement. Refer to the AL-4000 Instruction Manual.

3.5.3 Displaying and setting measurement points

This function displays and sets the location of measurement points.



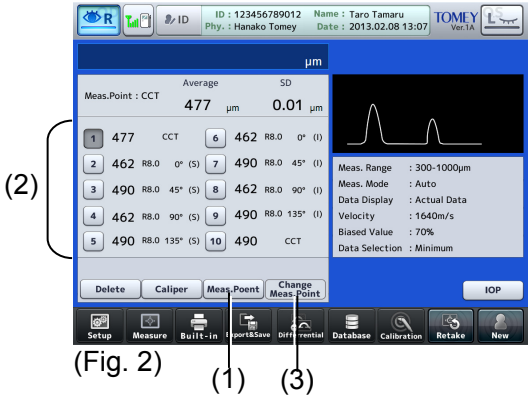
(Fig. 1)

The measurement point indicates “diameter – angle – S/I.”

- Radius : Radius from the center (mm)
- Angle : The upper and lower angles (°) when regarding the horizontal axis as zero degrees
- S/I : Section above the horizontal axis (Superior), section below the horizontal axis (Inferior)

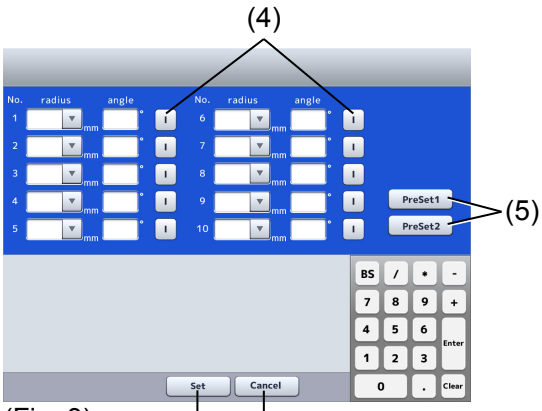
The center point is indicated as “CCT.”

1) Touch the "Meas Point" button (1) to display measurement points in the measurement data display field (2).



(Fig. 2)

2) Touch the “Change Meas. Point” button (3) to open the measurement point change screen (Fig. 3) to change the measurement point.



(Fig. 3)

3) When the desired input field on the measurement point change screen (Fig. 3) is touched, the field is activated. Set values using the keypad and the like. As for the setting of “S/I,” the indication switches between “S” and “I” each time the S/I button (4) is touched.

4) Touch the Preset button (5) to set the value preset in utility. (Refer to “3.9.2 c) Settings for various measurements.”)

5) Touching the “Set” button (6) will apply the changes made, and the measurement point change screen (Fig. 3) is closed. Touching the “Cancel” button (7) will cancel the changes made, and the measurement point change screen (Fig. 3) is closed.

3.5.4 Measurement

See the user’s manual of the AL-4000 for the actual procedure of measurement. This section describes the operations that can be performed with this instrument during measurement.

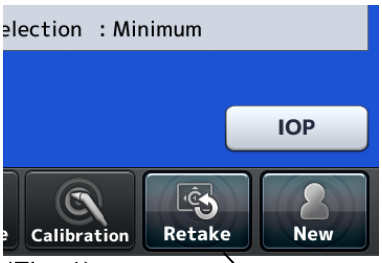
Note

- ***The converted acoustic velocity directly affects the measurement data. Check that the desired value is set before starting measurement.***
- ***The measurement data can be displayed as the actual measurement or a bias value. Check the setting of the data display mode.***
- ***The automatic measurement function is an auxiliary function to take measurements more easily and is not a function used to actually make clinical judgment. The physician must examine the measurement result before using it.***
- ***Be sure to touch the “New” button to delete all the measurement data of the previous patient before measuring another patient. If new measurement is started without deleting the previous data, the measurement data of the previous patient may be included.***

a) Re-measurement of the same patient

Note ■ ***The deleted data cannot be restored. Carefully check the data before deleting it.***

Retain the patient information and delete only the measurement data for each eye. Delete all data referring to “3.2.6 Clear all measurement data (preparation for measuring a new patient)” when the patient is changed.



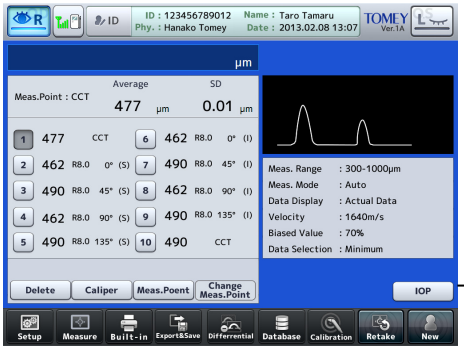
(Fig. 1) (1)

Touch the “Retake” button (1) for approximately 1 second until a beep sounds to delete the data. It retains the patient information and the measurement data of the eye other than the inspected eye being displayed.

3.5.5 Checking the measurement data

a) Intraocular pressure correction

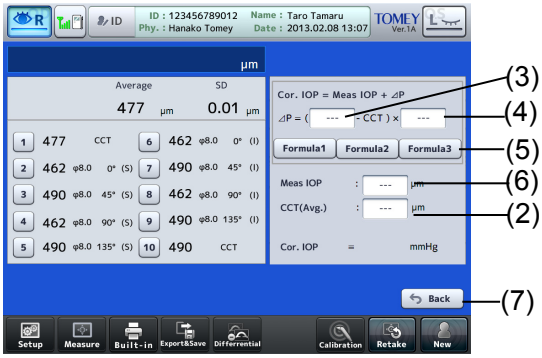
This instrument automatically starts calculation and displays the result when all items required for calculating the intraocular pressure correction are set.



(1)

(Fig. 1)

1) Touch the “IOP” button (1) to open the intraocular pressure correction screen (Fig. 2). When a measurement has already been completed at this point, the measured value is displayed in the CCT field (2).
However, if measurement points are set and two or more “CCTs” are included in them, the average of the CCTs is displayed. When measurement points are not set, the average of all memory numbers is displayed.



(Fig. 2)

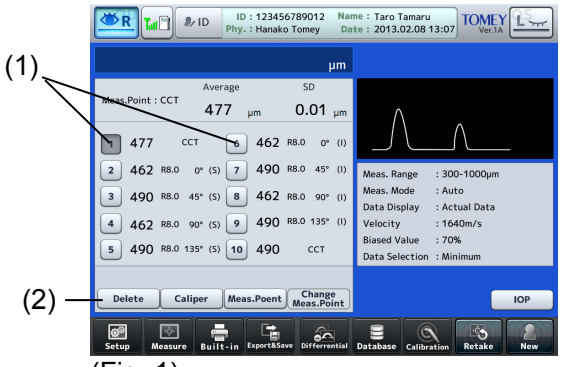
2) The input fields of the parameter 1 (3) and parameter 2 (4) for the intraocular pressure correction formula become active when touched, and the keypad appears. Also, when a formula selection button is touched, the already set parameters are displayed in the intraocular pressure correction formula.
[Input range]
■ Parameter 1 : 0 - 1500
■ Parameter 2 : 0.0000 - 1.0000

3) Enter the intraocular pressure data. The keypad appears when the entry field (6) is touched.

[Input range]
■ Intraocular pressure data : 1 - 60.0 (mmHg)
: 1.33 - 79.99 (hPa)

4) Touch the “Back” button (7) to close the intraocular pressure correction screen (Fig. 2) and return to the previous screen.

b) Deleting part of measurement data



(Fig. 1)

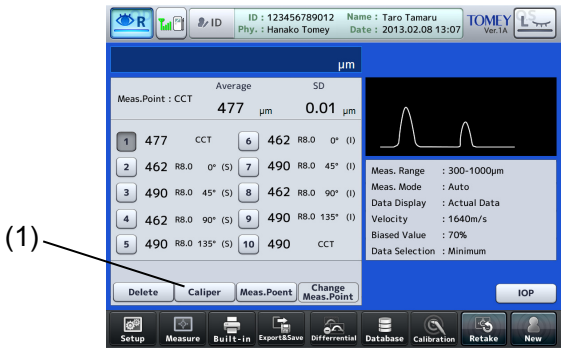
1) Touch a memory number button (1) to select the measurement data to be deleted.

2) Touch the “Delete” button (2) to delete the selected measurement data, and the average and the standard deviation of the corneal thickness are recalculated.

3) If you have deleted data mistakenly or want to cancel the deletion, select that data number and you will see that the “Delete” button (2) will change to the “Return” button. Touch the “Return” button to cancel the deletion. When new measurement data is captured, however, the deleted data cannot be restored by pressing the “Return” button.

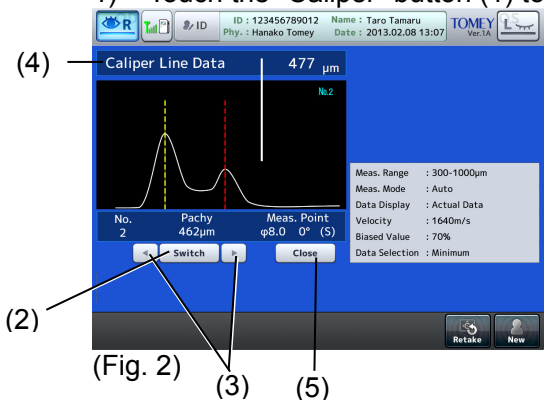
c) Caliper function

The caliper function is for temporary reference and cannot store the callipered data.



(Fig. 1)

1) Touch the "Caliper" button (1) to display the caliper screen (Fig. 2).



(Fig. 2)

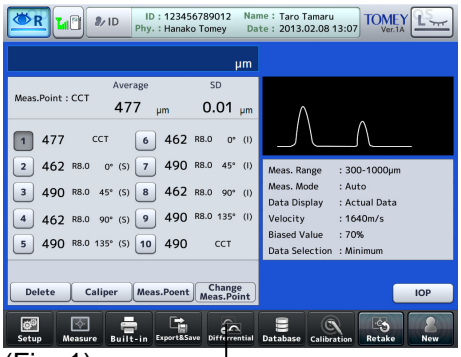
2) Touch the “Switch” button (2) to select a caliper line to be adjusted. The active caliper line is displayed in red and the other caliper line in yellow.

3) Touch the “active caliper line movement” button (3) to change the position of the active caliper line. In conjunction with the movement of the caliper line, the distance between the caliper lines (4) is displayed.

4) Touch the “Close” button (5) to close the caliper screen (Fig. 2) and return to the previous screen (Fig. 1).

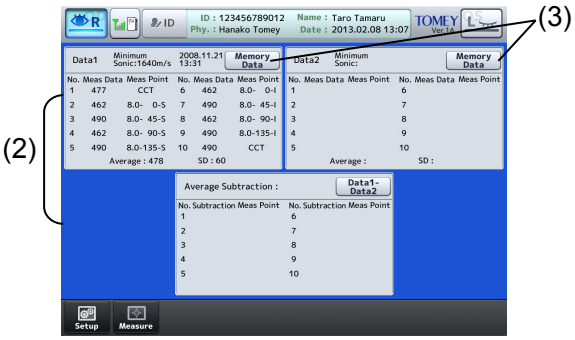
d) Subtraction display function

This function displays the difference value between the 2 selected measurement data.



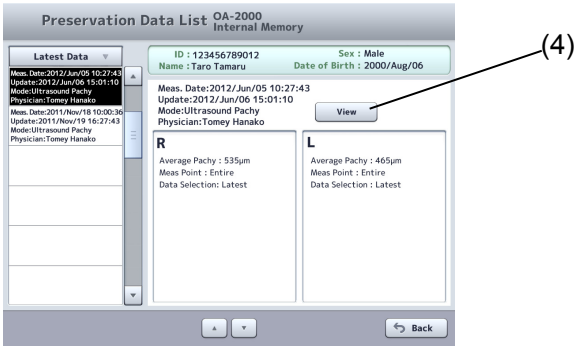
(Fig. 1)

1) Touch the “Differential” button (1) to open the subtraction display screen (Fig. 2). When a measurement has already been completed at this point, the measured values are displayed in the data 1 display field (2).



(Fig. 2)

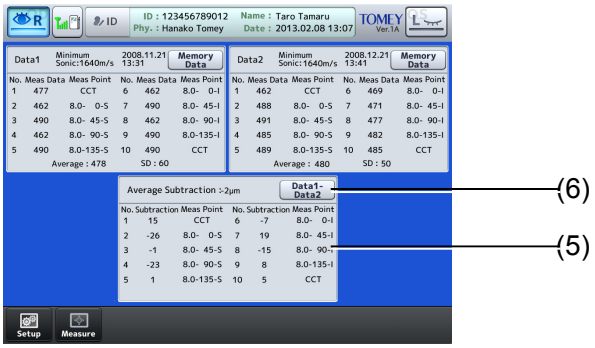
2) The measurement data being stored can be selected as Data 1 or Data 2. Touch the "Memory Data" button (3) to display a list of measurement data being stored in a USB memory. (Fig. 3) If a patient ID has not been selected, however, it displays a list of patient IDs stored in a USB memory. Refer to “3.8.3 Saved data management.”



(Fig. 3)

3) Touch the “Data Display” button (4) to display the selected measurement data in the subtraction display screen.

4) When measurement data are selected in Data 1 and Data 2, the difference value between Data 1 and Data 2 is displayed in the subtraction display field (5). If measurement points have been selected, however, only the difference values of the memory numbers whose measurement points match in both data are displayed.



(Fig. 4)

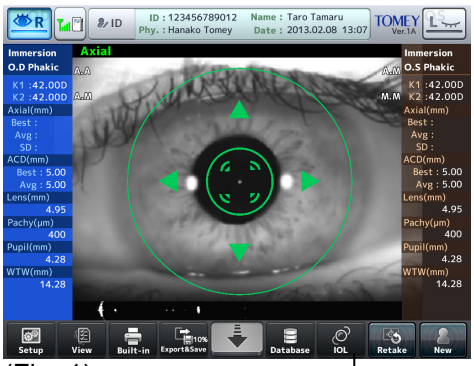
5) When the “Data 1 - Data 2” button (6) is touched, the indication on the button will change to “Data 2 - Data 1,” and the difference value of Data 2 - Data 1 will be displayed.

3.6 IOL power calculation

Note

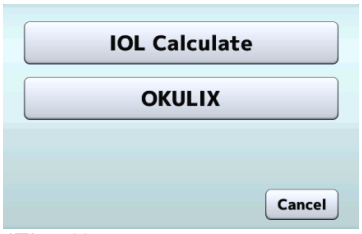
- ***When using biometry results for calculation of the IOL power, the physician must examine the measurement result beforehand.***
- ***Calculation by this instrument may cause some errors due to the number of significant digits in internal calculations.***
- ***Complex numbers may be generated for the SRK/T formula. In this case, the "√ section" is calculated as zero and an asterisk "*" is shown on the right of the calculation result.***
- ***Refer to "3.8 Export, print, and save" for waveforms printed and exported from the IOL calculation screen.***
- ***OKULUX calculates IOL power using keratometer measurement values. When no keratometer measurement value is available, the OKULIX screen does not open.***
- ***The OKULIX screen does not open when the OKULIX USB dongle is not connected to this instrument.***

This instrument automatically starts calculation and displays the result when all items required for IOL power calculation are set. In addition, this instrument is designed to execute 8 types of IOL power calculations and OKULIX calculation. Touch the "IOL" button and select the desired calculation on the selection screen (Fig. 2). The screen last selected will open automatically for the next operation. Touch the "IOL Selection" button (2) on each calculation screen to open another calculation screen.



(Fig. 1)

(1)



(Fig. 2)

IOL Calculate	Haigis standard formula Haigis optimized formula Hoffer® Q formula Holladay 1 formula SRK-II formula SRK/T formula SRK SHOWA formula Shammas-PL formula SRK/T Double K
OKULIX	OKULIX

(Fig. 3) (2)

3.6.1 Setting the eye to be measured

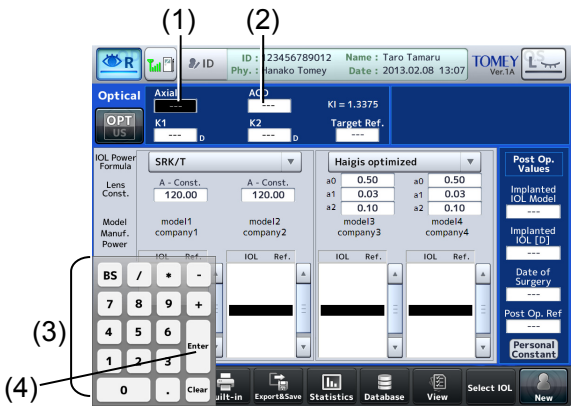
TRefer to “ 3.2.7 Selecting the eye ”

3.6.2 IOL power calculation

3.6.2.1 Entering **calculation parameters**

a) Axial length and anterior chamber depth

When an axial length and anterior chamber depth measurement is completed, the measurement data is already entered automatically and cannot be entered manually. (Refer to “3.4.3 e) Selecting specific measurement data to be used for calculating IOL power.") When measurement has not yet been performed, enter the data as follows.

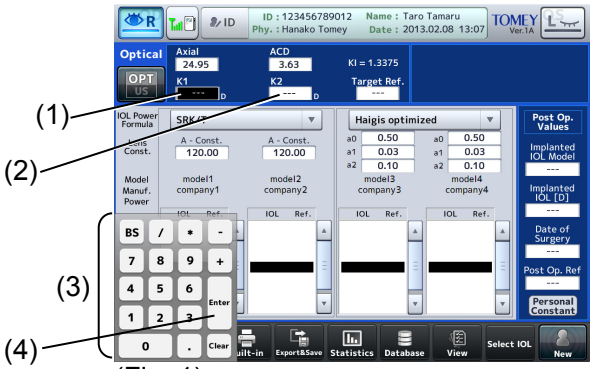


(Fig. 1)

1) Touch the axial length input field (1) or the ACD input field (2) to activate it. The keypad (3) appears. Touch the “Enter” key (4) to apply the data.
[Input range]
Axial length : 13.00 - 45.00 mm
Anterior chamber depth : 0.00 - 10.00 mm

b) Corneal refractive power and radius of corneal curvature (K1/K2)

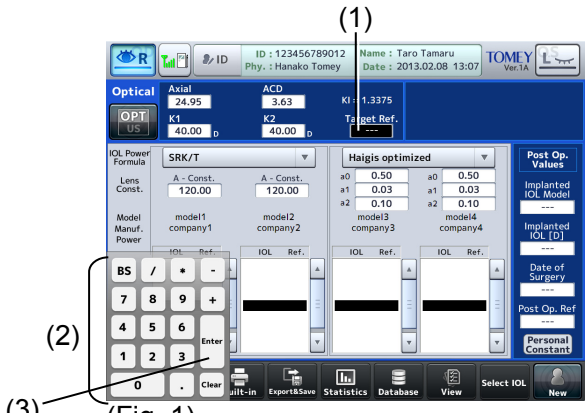
When keratometer measurement is completed, the measurement data is already entered automatically and cannot be entered manually. (Refer to “3.4.3 e) Selecting specific measurement data to be used for calculating IOL power.") When measurement has not yet been performed, enter the data as follows.



(Fig. 1)

1) Touch the K1 input field (1) or the K2 input field (2) to activate it. The keypad (3) appears. Touch the “Enter” key (4) to apply the data.
[Input range]
Corneal refractive power : 30.00 - 60.00D
Radius of corneal curvature : 5.00 - 11.00 mm

c) Target Ref.



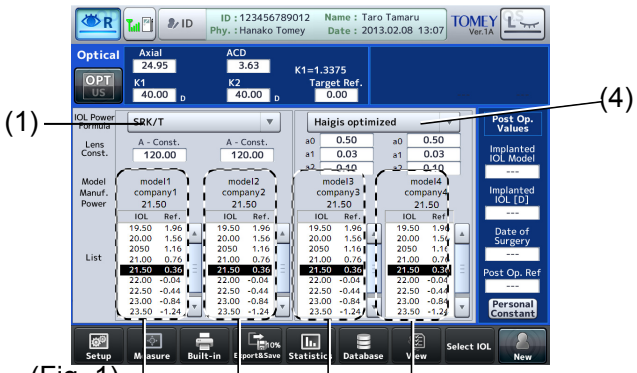
(Fig. 1)

1) Touch the Target Ref. input field (1) to activate it. The keypad (2) appears. Touch the “Enter” key (3) to apply the data.
[Input range] Angle : -30.00 – +10.00

The entered value is stored in the main unit, and is not cleared even when the power is turned off.

d) Lens constants (A-constant/SF/ACD-constant/a0・a1・a2)

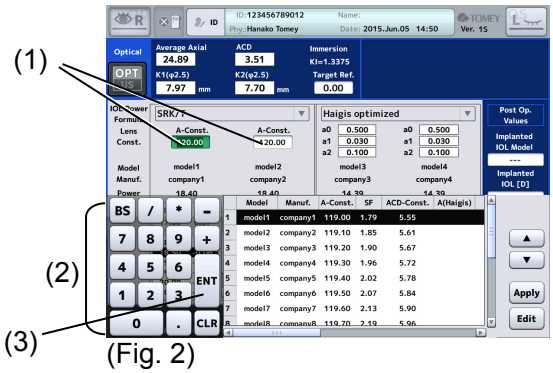
Enter various lends constants for IOL according to the formula. This instrument is able to calculate up to 4 constants for 1 formula simultaneously. The formula (1) corresponds to the lends (2) and (3), and the formula (4) corresponds to the lends (5) and (6). There are 2 ways to enter the values. One is to enter them directly using the keypad, and the other is by selecting them from the IOL data list.



(Fig. 1)

■ Entering using keypad

The lens constants a0, a1, and a2 in the Haigis optimized formula cannot be entered directly using the keypad. Refer to “Entering through IOL data list” below.



(Fig. 2)

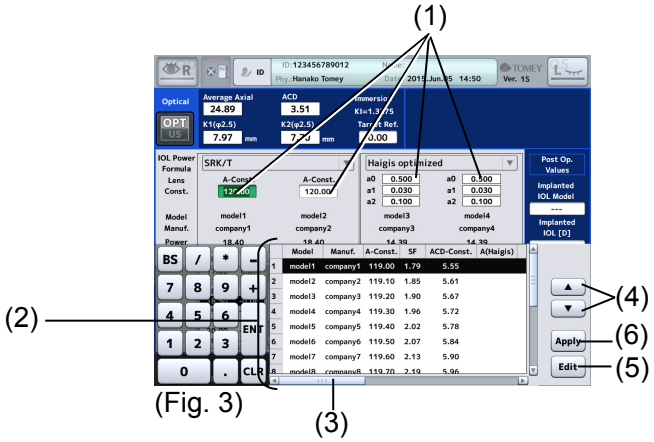
1) Touch an input field (1) to activate it. The keypad (2) appears. Touch the “Enter” key (3) to apply the data.

[Input range]

A-constant	: 100.00 - 130.00
ACD-constant	: 0.00 - +10.00
SF	: - 5.00 - + 10.00

■ Entering through IOL data list

When IOL data has already been registered in the “IOL data registration,” you can select data from the IOL data list.



(Fig. 3)

1) Touch an input field (1) to activate it. The IOL data list (2) appears.

2) You can check the registration content by sliding the IOL data list being displayed with the scroll bar (3).

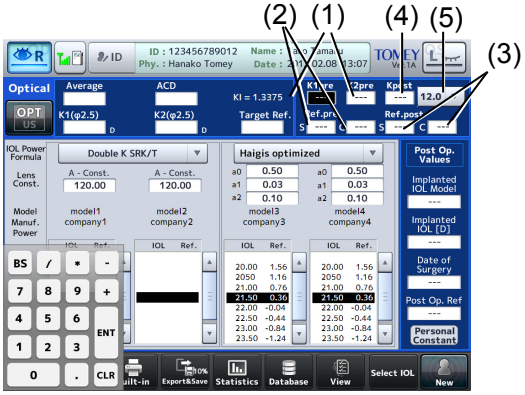
3) Select data using the “IOL data selection” buttons (4).

4) Touch the "Edit" button (5) to display the screen for editing the registration content.

5) Touch the “Apply” button (6) to apply the lens constants and to display them on the previous screen.

e) Entering parameters for Clinical History Method

Activated only when SRK/T Double K is selected as the formula.



(Fig. 1)

1) Enter the corneal refractive power or radius of corneal curvature before the surgery for correcting the refractive power in K1pre and K2pre fields (1).

2) Manually enter eye refractive power before refractive correction surgery in Ref.pre (S,C)(2) and eye refractive power after refractive correction surgery in Ref.post (S,C) (3).

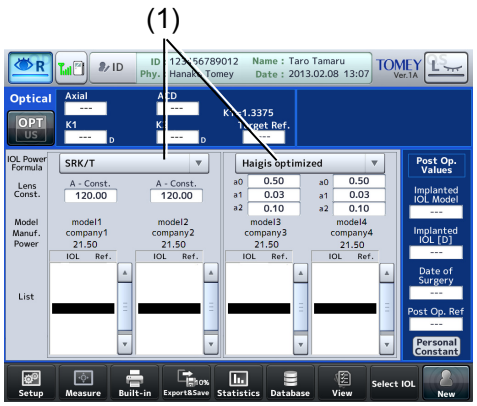
3) When values are entered in K1Pre, K2Pre, Ref.pre (S,C), and Ref.post (S,C), the calculation starts automatically and the corneal refractive power or radius of corneal curvature after the refractive power correction surgery is displayed in Kpost (4). The data can be entered directly. However, Ref.pre (S,C) and Ref.post (S,C) cannot be entered.

4) Select the distance between the vertexes (V.D.) from the pull-down menu (5). C.L./12.0/13.5/14.0/15.5/16.0

3.6.2.2 Setting calculation formula

Touch the calculation formula pull-down button (1) and select a formula.
The following 9 types of IOL power calculation formulae are provided with this instrument.
IOL calculation formulae listed in the pull-down menu can be set according to “3.9.3.b) Selecting IOL power calculation formula.”

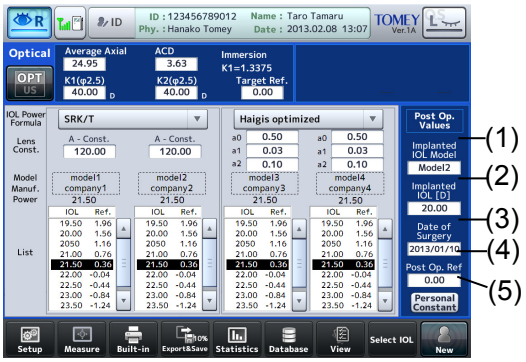
- Haigis standard formula
- Haigis optimized formula
- Hoffer® Q formula
- Holladay 1 formula
- SRK-II formula
- SRK/T formula
- SRK SHOWA formula
- Shammas-PL formula
- SRK/T Double K formula



(Fig. 1)

3.6.2.3 Entering data after surgery

Select the name of the IOL type that was actually implanted in the surgery.

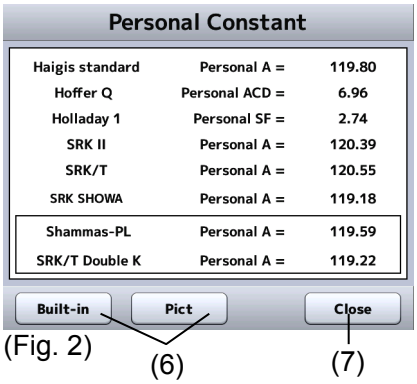


(Fig. 1)

1) Select the type of implanted IOL. When the entry field (1) is touched, it is activated. Select the name of the IOL type that was actually implanted in the surgery from the IOL list.

2) Enter the implanted IOL power (2), date of surgery (3), and refractive power after surgery (4). The keypad or calendar appears when the input field is touched.

3) When the “Personal Constant” button (5) is touched, the Personal Value screen (Fig. 2) appears. Touch the “Print” button (6) to print the personal constants only. Touch the “Close” button (7) to close the Personal Value screen and return to the previous screen.



(Fig. 2)

3.6.3. OKULIX

Note

■ ***When using the OKULIX calculation result to select IOL, thoroughly determine the selection by also examining cataract surgery methods, other inspections and other IOL power calculation formulas. In particular, in the case of the cornea of a sound eye without having surgery to correct refractive power of the cornea such as LASIK, carefully compare the OKULIX calculation result with the result of SRK/T formula etc. and, if there is a large difference, examine them with due care.***

a) Entering axial length, ACD endothelium and lens

When an axial length and anterior chamber depth measurement is completed, the measurement data is entered automatically and cannot be entered manually.

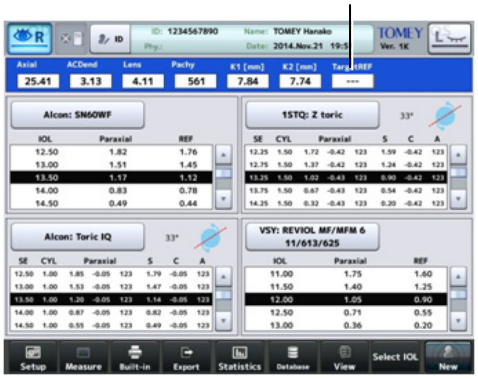
(1) (2) (3)

(Fig. 1)

1) Touch the axial length input field (1), the ACD endothelium input field (2) or the lens input field (3) to activate it. The keypad appears. Enter the data and touch the “Enter” key on the keypad to apply the data.

b) Entering target Ref.

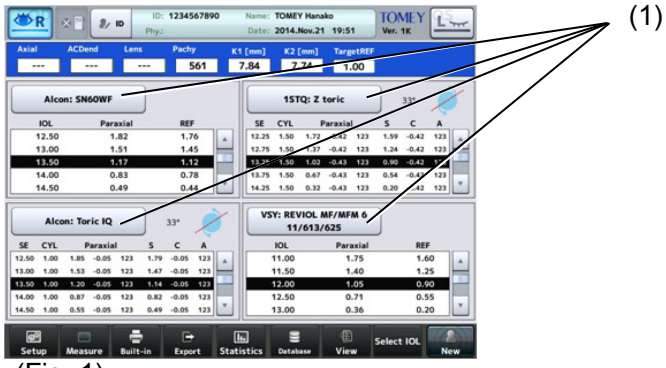
(1)



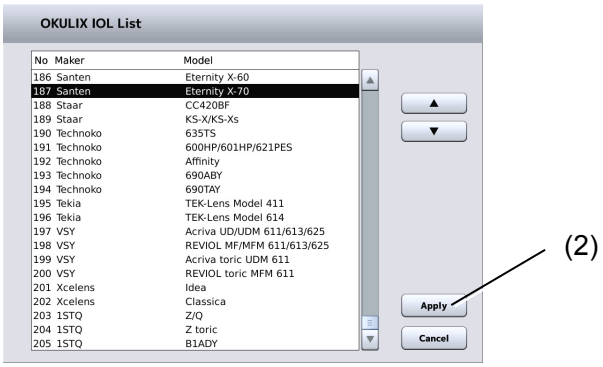
(Fig. 1)

1) Touch the Target Ref. input field (1) to activate it. The keypad appears. Enter the data and touch the “Enter” key on the keypad to apply the data. The entered value is stored in the main unit, and is not cleared even when the power is turned off.

c) Selecting IOL



(Fig. 1)



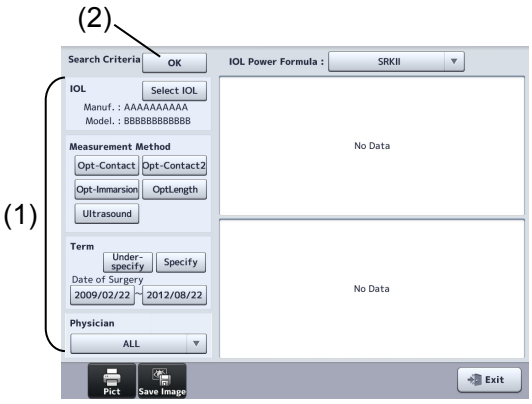
(Fig. 2)

1) Touch the IOL data field (1). The IOL List screen (Fig. 2) appears and allows you to select the desired IOL data. Select the data and touch the “Apply” key (2) to apply the data.
The entered value is stored in the main unit, and is not cleared even when the power is turned off.

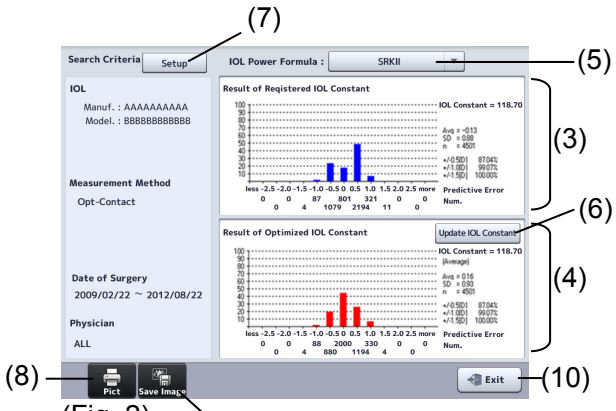
3.7 Statistical processing

Note ■ ***The lens constant registered on this screen will be used for the next IOL calculation. Carefully check the data before registration.***

Statistical processing can be performed on this screen using the examination data accumulated in the facilities. Predictive errors when using the registered lens constant are calculated and the histogram is displayed. In addition, the optimized lens constant can be calculated and registered according to the statistical processing result.
Calculation results when lens constants are entered manually are excluded from statistical processing.



(Fig. 1)



(Fig. 2)

1) Set filter conditions (1) for targets subject to statistical processing.

IOL	:	Select IOL. Touch the “Select IOL” button. The IOL data selection screen appears to allow you to select an IOL model.
Measurement Method	:	Optical-contact / Optical-contact 2 / Optical-immersion / Optical path length / Ultrasound
Term (data extraction term)	:	Set the term subject to statistical processing.
Physician	:	The registered physician IDs are displayed in the pull-down menu. “All” includes all physicians.

2) After all the conditions are set, touch the “OK” button (2). Statistical processing is performed and the result appears on the right side of the screen.
The histogram (3) in the upper section shows registered lens constants and the statistical processing results of those lens constants. When lens constants are not registered, the result does not appear.
- Registered lens constant
- Histogram of predictive error in refractive power
- Average of predictive error in refractive power (Avg)
- Standard deviation of predictive error in refractive power (SD)
- No. of data sets (n)
The histogram (4) in the lower section shows the average of lens constants optimized by statistical processing and predictive results of processing when the average is used.
- Average (Avg) of optimized lens constant
- Histogram of predictive error in refractive power
- Average of predictive error in refractive power (Avg)
- Standard deviation of predictive error in refractive power (SD)
- Number of data (n)
- Percentage that predictive errors in refractive power fall under +/-0.5 [D], +/-1.0 [D], or +/-1.5 [D]

3) Select an IOL power formula (5). Available formulae are as follows.

- Haigis standard formula
- Haigis optimized formula
- Hoffer® Q formula
- Holladay 1 formula
- SRK-II formula
- SRK/T formula
- SRK SHOWA formula
- Shammas-PL formula
- SRK/T Double K formula

4) Click the “Update IOL Constant” button (6) to register the optimized lens constant for the target manufacturer, model, physician, and formula. When the button is touched, the IOL data change confirmation screen appears. Click the “OK” button to complete registration.

5) Touch the “Setup” button (7) to re-set filter conditions.

6) Touch the “Print” button (8) to print the displayed results. Touch the "Save Image” button (9) to save the displayed result as an image file.

7) Touch the “Exit” button (10) to close the statistical processing screen.

3.8 Export, print, and save

Set desired functions to 2 buttons for export, print, and save provided on the operation screen before executing the export, print, and save functions. (Refer to "3.9.4 a) Setting functions of save, export, and print buttons.")
The print and export buttons work according to the preset functions when touched after measurement.

(Fig. 1)

Button 1 Button 2

Export	Export	Built-in	Print
Save	Save	Export&Save	Export&Save
Export&Int.	Export&Print	Save&Int.	Print&Save
ALL(Int.)	ALL (export, print, and save)		

3.8.1 Export

Note

- ***The network support system "TOMEY Link" (optional) or the inspection data receiving software "DATA Transfer" (included in the package) is required for data communication.***
- ***Refer to the corresponding operation manual for the TOMEY Link and DATA Transfer settings.***
- ***Connection setting is required for connecting with TOMEY Link and DATA Transfer. Refer to "3.9.4 d) PC connection settings" to make settings.***
- ***Data cannot be sent in some configurations if the ID number is not entered. Refer to "3.9.1 General."***
- ***It is recommended to send data after entering the ID number. The data can be sent without ID numbers entered; however, the corresponding patient may not be traced from the inspection file output from DATA Transfer. When the data was sent without entering the ID number, check the content of the inspection file immediately after sending the data, and move and save the file in an appropriate location. In addition, when data was sent to TOMEY Link, all the data without ID number are regarded as the data of the same patient so that they must be handled with great care to avoid mishandling.***
- ***Waveforms of the same form as those to be printed out are output.Refer to "3.8.2 Printing" for details.***

1) Touch the “Export” button (1) to open the Transmission confirmation screen (Fig. 2).

(Fig. 1)

(1)

(Fig. 2)

(2) (3)

2) The transfer confirmation screen (Fig. 2) displays patient ID, patient name, and sex. Touch the "Send" button (2) to start sending data.
Touching the "Cancel" button (3) returns you to the previous screen without sending data.

3) When data transfer is completed, the message “Complete” appears. If an error is displayed, refer to “6. Troubleshooting.”

3.8.2 Printing

The printer and printing type can be selected in the system setup. Refer to "3.9.4 b) Selecting and setting printer."

Note ■ ***Different waveforms are printed depending on the screen.***

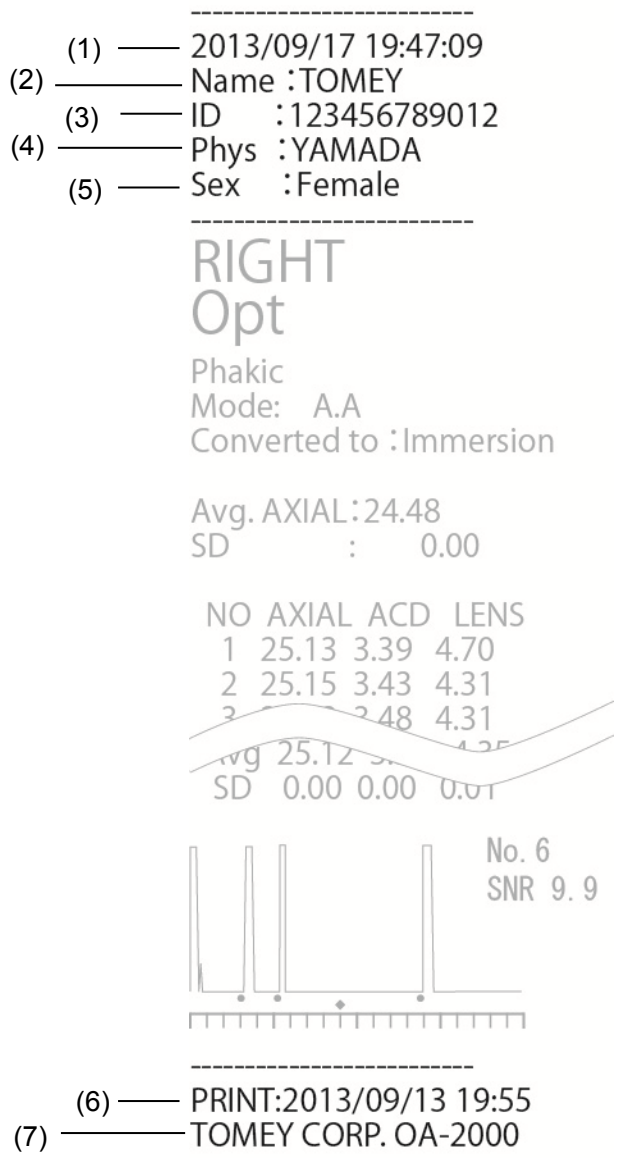
Optical mode

Measurement screen : Waveform No. 1 is printed.
View screen : Waveform displayed on the screen is printed.
IOL screen : Waveform No. 1 is printed when entering the IOL screen from the measurement screen. The waveform displayed on the view screen is printed if entering the IOL screen from the view screen.

Ultrasound (US) mode

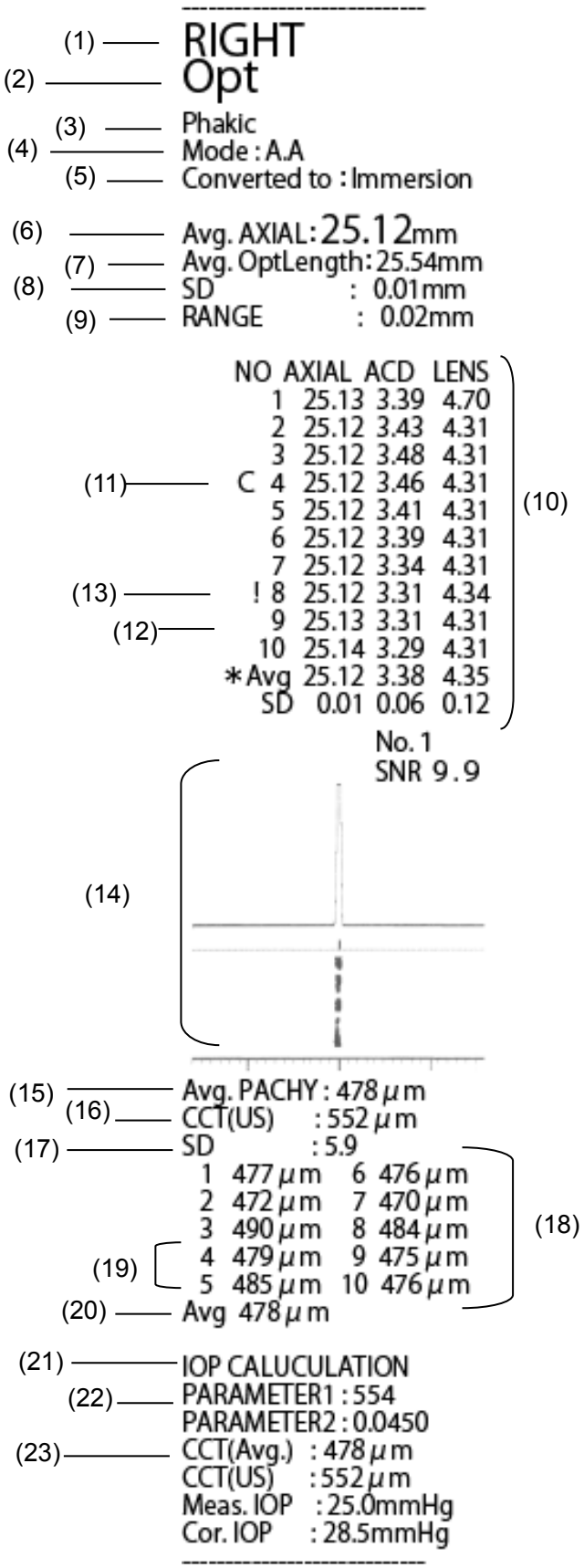
Measurement screen : The waveform which is the closest to the average is output.
View screen : Waveform displayed on the screen is printed.
IOL screen : The waveform the closest to the average value is printed when entering the IOL screen from the measurement screen. The waveform displayed on the view screen is printed if entering the IOL screen from the view screen.

a) Common items



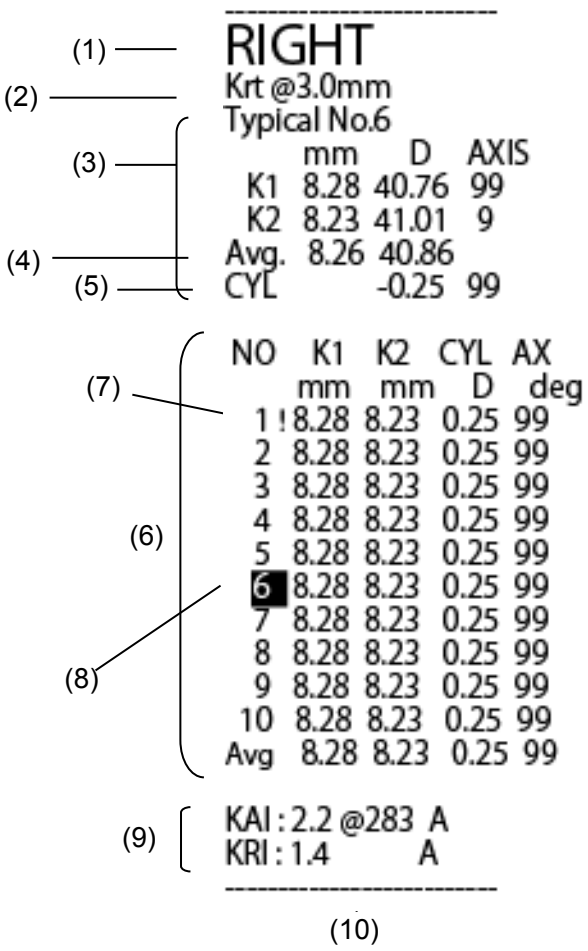
1) Measurement date and time
2) Patient name
3) Patient ID
4) Physician name
5) Sex
6) Printed date and time
7) Product Name

b) Example of printout for optical (axial length, anterior chamber depth, lens, corneal thickness)



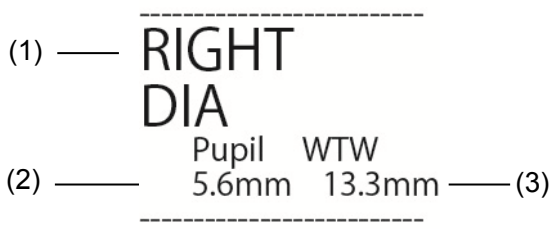
1) Inspected eye (right eye/left eye)
2) Measurement method
3) Inspection eye
4) Measurement mode
   Auto (A) / Manual (M)
5) Fitting
   Immersion / Contact / Optical length
6) Average axial length
7) Average optical distance
8) Standard deviation of axial length
9) Difference between shortest axial length and longest axial length
10) Axial length, anterior chamber depth, measurement value of lens
11) Caliper mark
12) Value used for IOL calculation
13) Low reliability mark
14) Waveform
15) Average corneal thickness
16) Ultrasound correction for corneal thickness
17) Standard deviation of corneal thickness
18) Corneal thickness measurement value
19) Intraocular pressure correction parameter
20) Average corneal thickness
21) Ultrasound correction for corneal thickness
22) Intraocular pressure
23) Corrected intraocular pressure

c) Example of printout for optical measurement (kerato)



1) Inspected eye (right eye/left eye)
2) Kerato measurement position
3) Selected measurement value
4) Keratometer average value
5) Corneal astigmatism
6) Measurement value
7) Low reliability mark
8) Memory number of representative value
9) Corneal irregular astigmatism index
10) Corneal irregular astigmatism angle

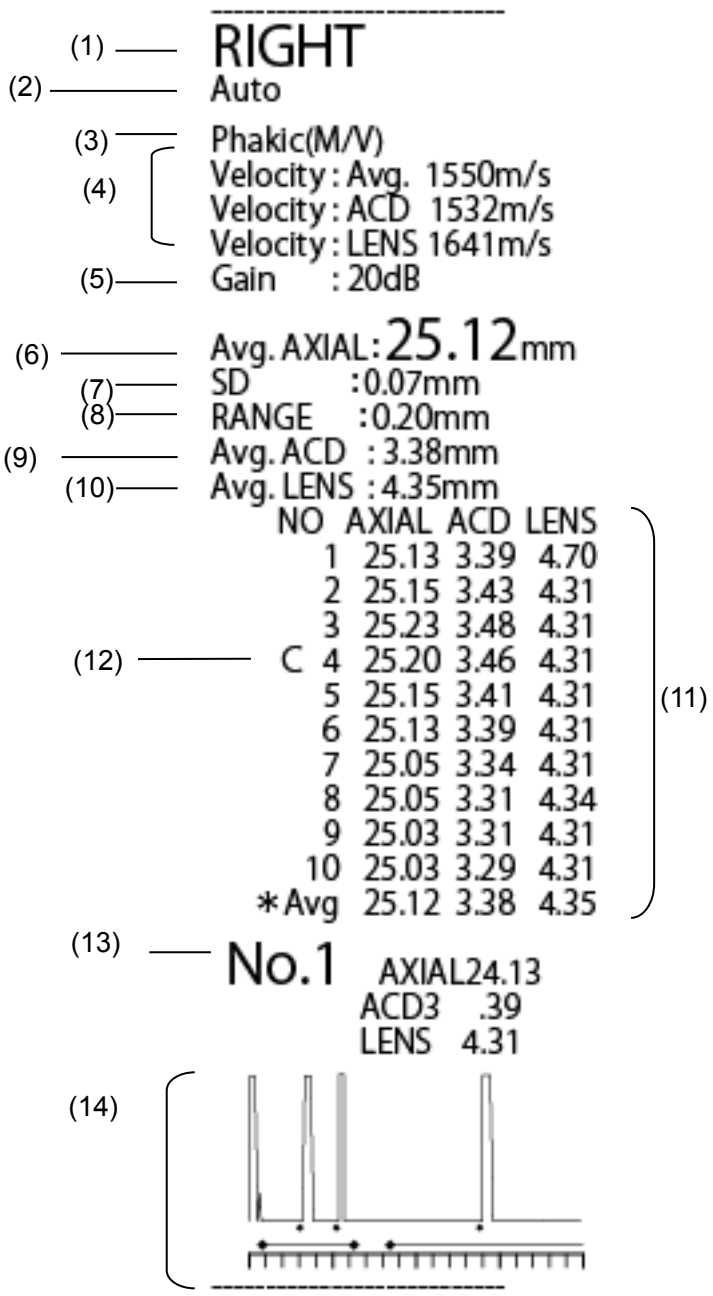
d) Example of printout for optical measurement (pupil/corneal diameter)



1) Inspected eye (right eye/left eye)
2) Pupil diameter
3) Corneal diameter

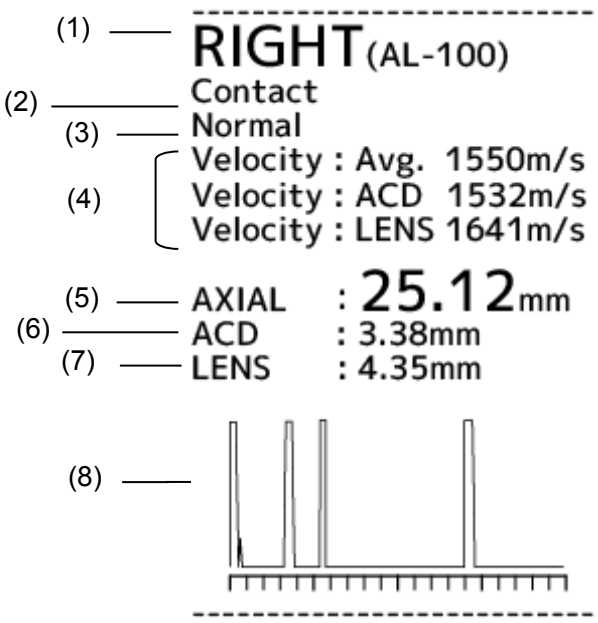
e) Example of printout for ultrasound measurement (axial length)

[AL-4000]



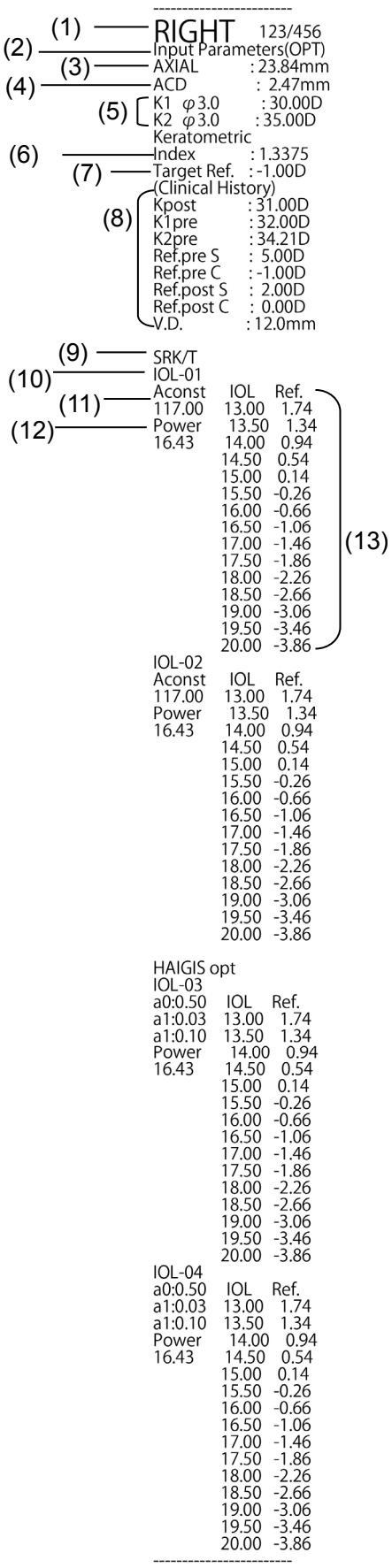
1) Inspected eye (right eye/left eye)
2) Measurement method
3) Inspection eye
4) Converted sonic velocity
5) Gain
6) Average axial length
7) Standard deviation of axial length
8) Difference between shortest axial length and longest axial length
9) Average anterior chamber depth
10) Average lens thickness
11) Measurement data (axial length/anterior chamber depth/crystal lens thickness)
12) Caliper mark
13) Value used for IOL calculation
14) Waveform

[AL-100]



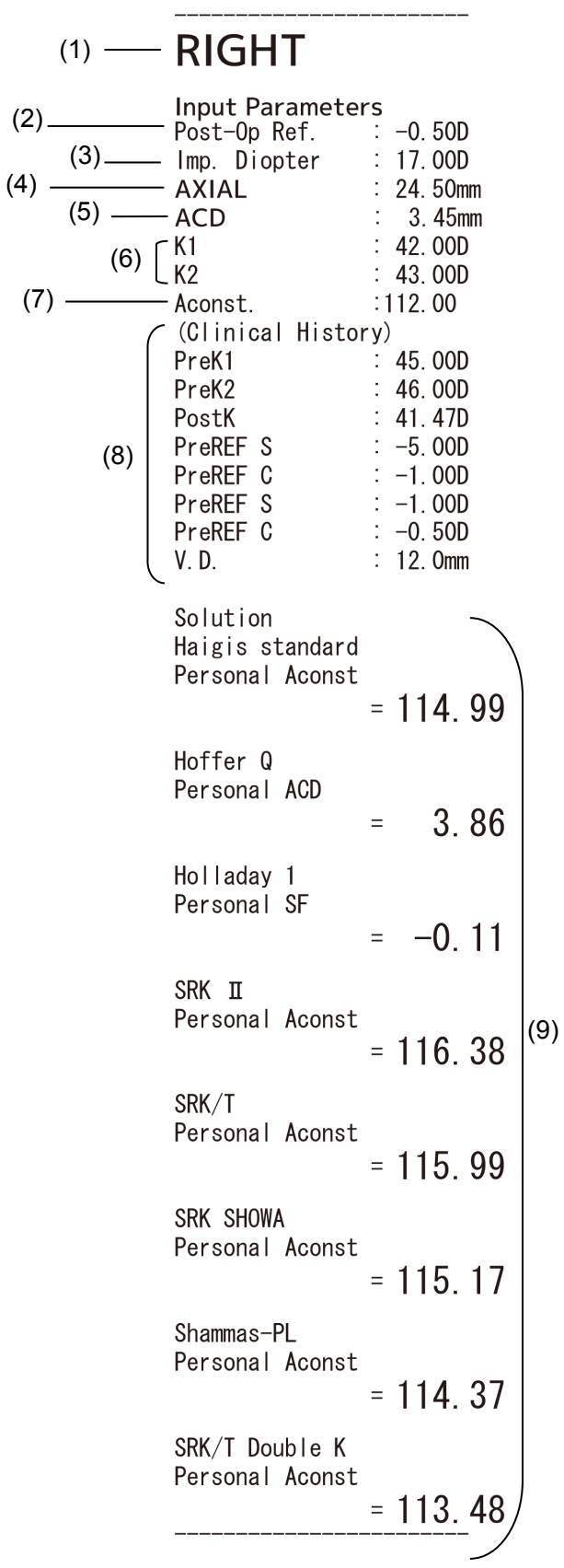
1) Inspected eye (right eye/left eye)
2) Model of measuring instrument
3) Patient's eye
4) Converted sonic velocity
5) Axial length
6) ACD (anterior chamber depth)
7) Lens thickness
8) Waveform

f) Printout of IOL power calculation



1) Inspected eye (right eye/left eye)
2) US/OPT display
3) Axial length
4) ACD (anterior chamber depth)
5) Corneal refractive power or radius of corneal curvature
6) Cornea equivalent refractive index
7) Target Ref. after surgery
8) Parameters printed when SRK/T Double K is selected
9) Formula name
10) IOL model name
11) Lens constant
12) Calculation result
13) IOL standard (15 levels) and estimated refractive power after surgery

g) Printout of personal constants



1) Inspected eye (right eye/left eye)
2) Eye refractive power after surgery
3) Power of the implanted IOL
4) Axial length
5) ACD (anterior chamber depth)
6) Corneal refractive power or radius of corneal curvature
7) Lens constant
8) Parameters for SRK/T Double K
9) Calculation result

3.8.3 Saved data management

a) Selecting storage

The internal memory of this instrument or external memory connected to this instrument can be selected.
Set the storage referring to “3.9.4 c) Media options / Data output format.”
When the internal memory is selected for storage, the used storage capacity is shown as a % on the button.
If the used storage capacity exceeds 90%, the value turns red.

b) Saving

Note ■ ***Always enter the ID number when saving the measurement data.***

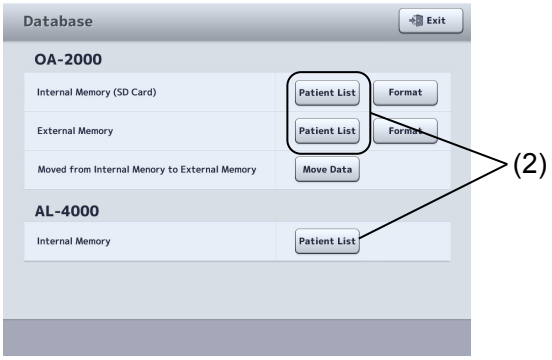
Touch the “Save” button (1) on each screen to save the data to the selected storage.

(Fig. 1)
(1)

c) Browsing saved data

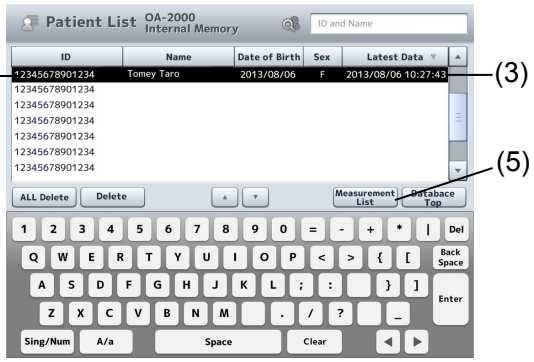
1) Touch the “Database” button (1) on each screen to open the Database screen (Fig. 2).

(Fig. 1)
(1)



(Fig. 2)

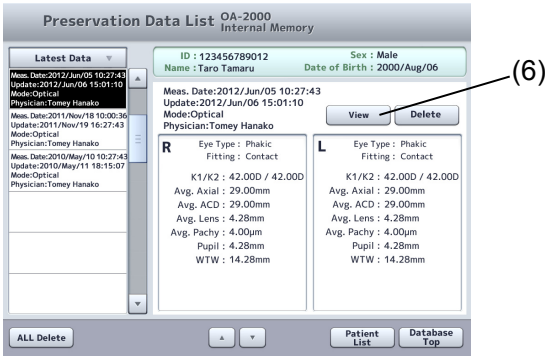
2) Touch the "Patient List” button (2) to display the Patient List screen (Fig. 3) of the internal memory of this instrument, external memory, and internal memory of AL-4000.



(Fig. 3)

3) When characters are entered in the search field (3), the patient ID and name are searched and the result appears. Touch the title of the line (4) to change the order of the list. Touching this button sorts the data in ascending order or descending order.

4) Touch the “Measurement List” button (5) to open the Preservation Data List (measurement data list of selected patient ID) screen (Fig. 4).



(Fig. 4)

5) Touch the "View" button (6) to display the view screen (Fig. 5). The data can be viewed and edited on this screen.

(Fig. 5)

6) Touch the “Over Write” button (7) to overwrite the existing data with the edited contents.

7) Touch the “Meas. List” button (8) to return to the Preservation Data List screen (Fig. 4).
Touch the “Patient List” button (9) to return to the Patient List screen (Fig. 3).

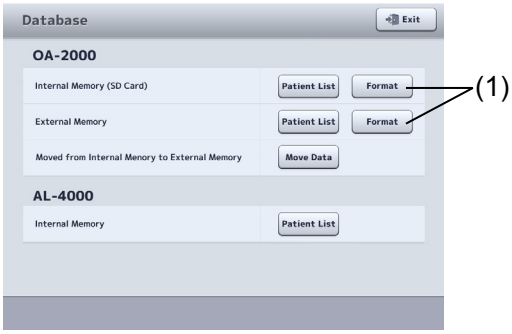
d) Deleting saved data

Note

■ ***When any patient information is deleted, all the measurement data saved with the patient ID is also deleted, regardless of the mode being displayed. Be sure to check the contents saved before deleting them.***

[Delete all on Database screen]

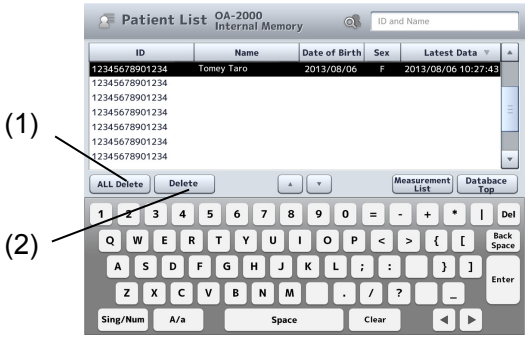
Touch the “Format” button (1). The confirmation window opens. Execute formatting to delete all the saved data.



(Fig. 1)

[Deleting data on Patient List screen]

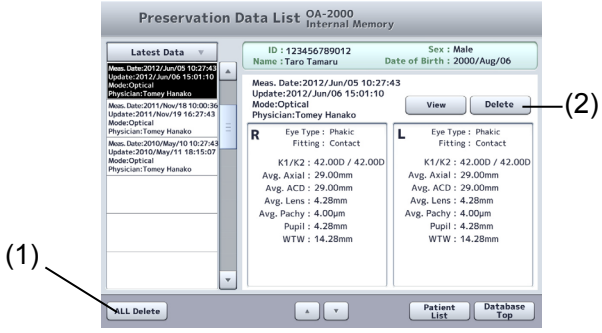
Touch the “ALL Delete” button (1). The confirmation window opens.Execute ALL Delete to delete all the data saved in the displayed storage.Touch the “Delete” button (2) to delete the selected patient ID and measurement data.



(Fig. 1)

[Deleting data on Preservation Data List screen]

Touch the “ALL Delete” button (1) to delete the selected patient ID and measurement data, and return to the Patient List screen. Touch the “Delete” button (2) to delete the selected measurement data only.



(Fig. 1)

e) Transferring saved data

Note

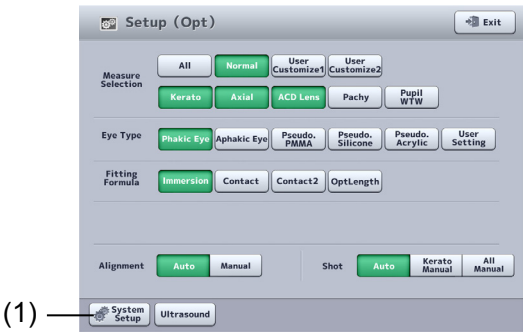
■ ***Some USB flash memories are not recognized when connected to this instrument.***

When an external memory is connected to this instrument, the data saved in the internal memory can be transferred to the external memory.
Touch the “Move Data” button (1) to start transferring the data.
The transferred data is completely deleted from the internal memory.

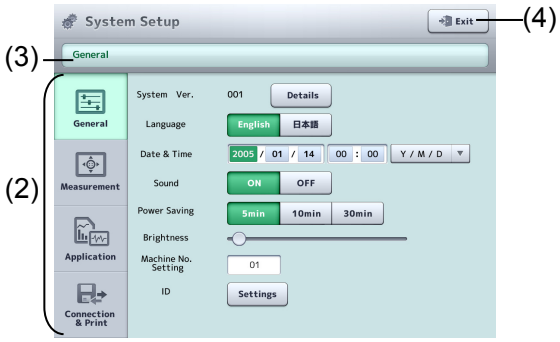
(Fig. 1)

3.9 System setup

Touch the “System Setup” button (1) on the Setup screen (Fig. 1) in each mode to open the System Setup screen (Fig. 2).



(Fig. 1)



(Fig. 2)

1) The system setup consists of 4 major categories.

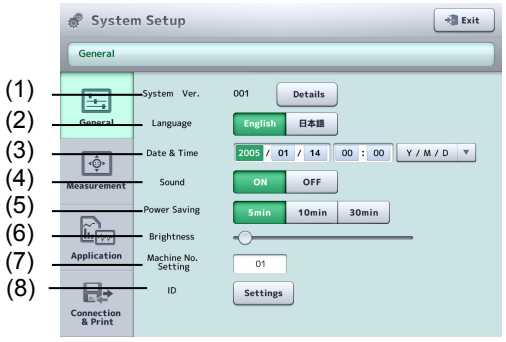
- General.....Language, time, version information, etc.
- Measurement.....Settings related to measurement
- Application .....Calculation, analysis, and correction
- Connection & Print.....Connection and printing

Touch the menu tab (2) to open the corresponding setup screen.
The setup screen is configured as a tree. The displayed location is shown in the address bar (3) and you can jump to the specified screen by touching the displayed characters.

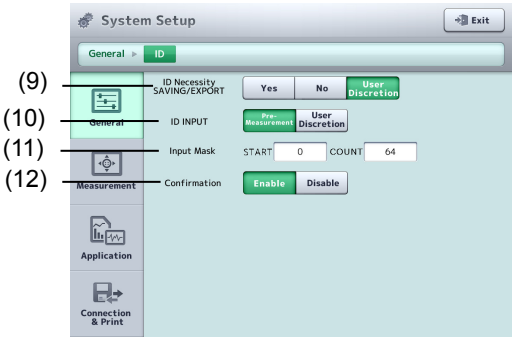
2) Touching the “Exit” button (4) will reflect the changes made and open the measurement screen.

3.9.1 General

Set common items here. Select the General tab.



(Fig. 1)



(Fig. 2)

(1) System Ver.
Displays the version information. The version information of the ultrasound measurement unit AL-4000 is also displayed.

(2) Language
Selects the language.

(3) Date & Time

Set the display format of the date and the date and time. The key pad appears when the input field is touched.

(4) Sound

Set whether to generate sound when operating the screen.

(5) Power Saving

This function automatically turns off the LCD when the instrument is not operated for a specified time. Touch the monitor screen to return to normal status.

Sets the time to automatically turn off the LCD.

5 mins / 10 mins / OFF

(6) Brightness

Set the brightness of the monitor screen.

(7) Machine No. Setting

Set the number to identify each instrument when multiple instruments of the same model are installed.

(8) ID

Open the setup screen for patient IDs.

(9) ID Necessity SAVING/EXPORT

Set how the patient ID must be handled when saving and sending examination data to TOMEY Link.

Indispensable	:	Select this when ID numbers are always required. Data cannot be saved or sent when the ID is not entered.
Yes	:	Select this when the ID is usually entered, but data can also be saved and sent without entering the ID. Data is saved and sent with the ID as “No ID” when the ID is not entered.
No	:	Select this when no special attention is paid to entry of the ID. The transfer confirmation screen appears, but the inspection data is automatically saved and sent. Data is saved and sent with the ID as “No ID” when the ID is not entered.

(10) ID INPUT

Set whether to display the patient information input screen before measurement when starting measurement for a new patient.

Pre-Measurement	:	Displays the patient information entry screen before starting measurement.
User Discretion	:	Displays the measurement screen.

(11) Input Mask

Sets which part of the character string should be recognized as the ID number when entering the ID number from a barcode. If it starts from “0” or “1”, the characters from the very beginning are identified as the ID number.

(12) Confirmation

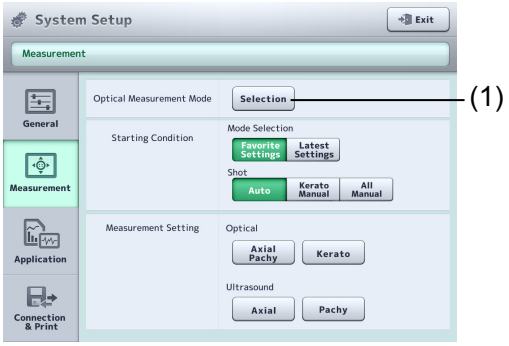
Use this field to display the Patient information confirmation screen when saving the inspection data or sending the inspection data to TOMEY Link.

3.9.2 Measurement

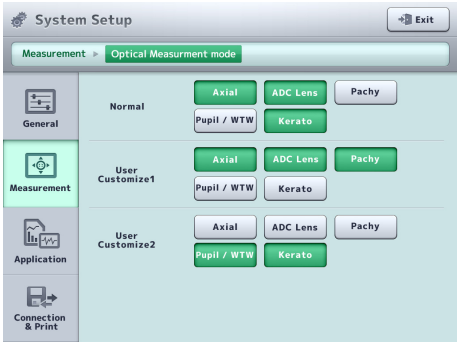
Make settings related to measurement on this screen. Select the Measurement tab.

a) Optical Measurement Mode - Selection

Select measurements to be performed in optical mode. Touch the “Selection” button (1) to open the measurement mode setup screen (Fig. 2).

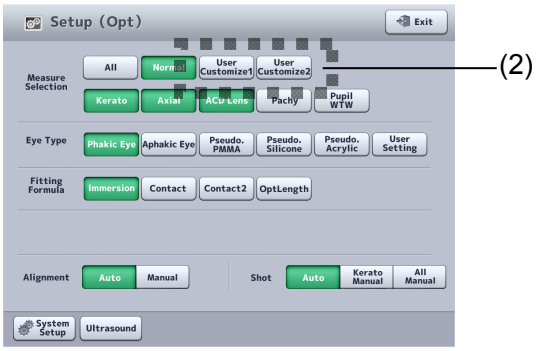


(Fig. 1)



(Fig. 2)

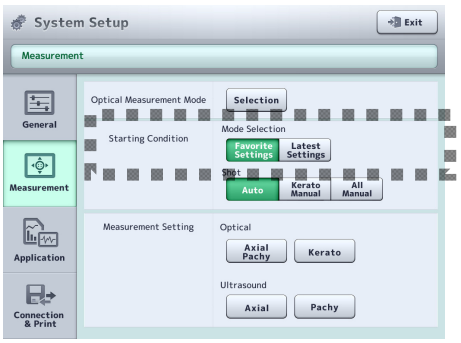
3 patterns can be prepared. Measurement modes selected here will be effective when specified in Measure Selection (2) on the Setup screen (Fig. 3).



(Fig. 3)

b) Starting Condition

Set the measurement mode when power is turned on and when the measurement mode is switched.

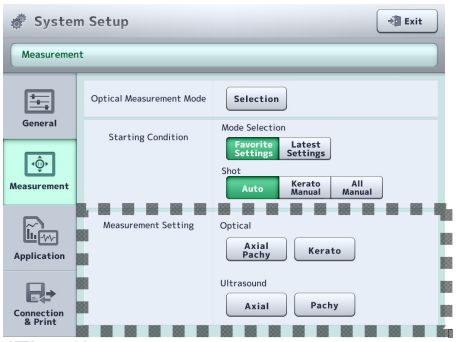


(Fig. 1)

Favorite Settings : The system starts with measurement contents selected on the mode selection screen.

Latest Settings : The system starts with measurement contents active when power was turned off last time.

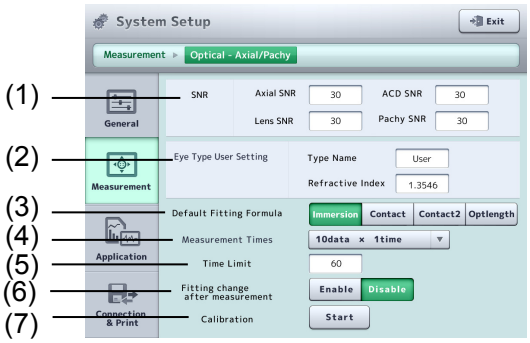
c) Settings for various measurements



(Fig. 1)

[Optical]	Axial Pachy / Kerato	:	Opens the setup screen for optical measurement of axial length and corneal thickness.
	Kerato	:	Opens the setup screen for keratometer measurement.
[Ultrasound]	Axial	:	Opens the setup screen for ultrasound measurement of axial length.
	Pachy	:	Opens the setup screen for ultrasound measurement of corneal thickness.

[Optical – Axial/Pachy]



(Fig. 1)

(1) SNR

Assigns a low reliability mark to data with an SNR smaller than the preset value.

			Input range	Default setting
Axial SNR	:	SNR of retina waveform	2～99	3
ACD SNR	:	SNR of waveform on the front of crystal lens	2～99	3
LENS SNR	:	SNR of waveform on the back of crystal lens	2～99	3
Pachy SNR	:	SNR of waveform on the back of cornea	2～99	3

(2) Eye Type User Setting
Set the average refractive index of the eye to be measured.

(3) Default itting formula
Set the fitting formula for normal operation.
Contact / Contact 2 / Immersion / Optilength
This selection changes the default view for the kerato measurement position.
Immersion: φ2.5 mm
Other fitting fomula: φ3.0 mm

(4) Measurement Times
Set the number of data sets taken per measurement.

10 data x 1 time	:	Load 10 data sets once.
5 data x 2 times	:	Load 5 data sets twice.

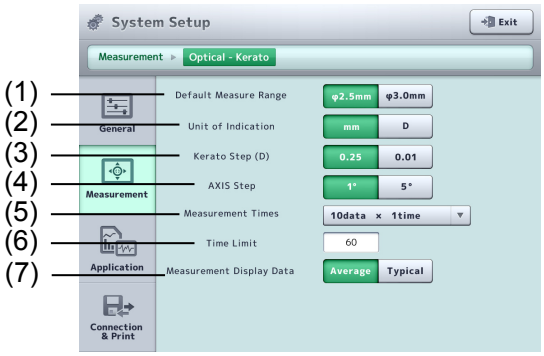
When “5 data x 2 times” is selected in auto measurement mode, 5 data sets are loaded after alignment is completed and measurement starts. Then, alignment is performed again, 5 data sets are loaded, and measurement is completed.

(5) Time Limit
Set the time limit for loading the preset number of datasets.
Input range: 10 – 60 (s)

(6) Changing fitting after measurement
Set whether or not the fitting change is permitted.

(7) Calibration
Calibrate the system.Perform calibration when measurement requires long time suddenly or measurement values are obviously faulty.

[Optical – Kerato]



(Fig. 1)

(1) Default Measure Range
Set a normal measurement position.
φ2.5 mm /φ3.0 mm

(2) Unit of Indication
Set the unit normally used for indications.
mm / D

(3) Kerato Step (D) (unit for measurement – diopter)
Sets the indication units for the measurement value of corneal refractive power.
0.25 / 0.01

(4) AXIS Step (unit for angle)
Sets the display units for the corneal astigmatism axial angle.
1° / 5°

(5) Measurement Times
Set the number of data sets taken per measurement.

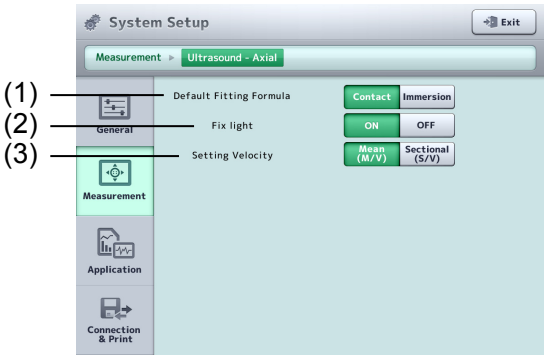
10 data x 1 time	:	Load 10 data sets once.
5 data x 2 times	:	Load 5 data sets twice.
3 data x 3 times	:	Load 3 data sets 3 times.
3 data x 1 time	:	Load 3 data sets once.
1 data x 5 times	:	Load 1 data set 5 times.
1 data x 10 times	:	Load 1 data set 10 times.

When “5 data x 2 times” is selected in auto measurement mode, 5 data sets are loaded after alignment is completed and measurement starts. Then, alignment is performed again, 5 data sets are loaded, and measurement is completed.

(6) Time Limit
Set the time limit for loading the preset number of datasets.
Input range : 10 – 60 (s)

(7) Measurement Display Area
Average / Typical

[Ultrasound – Axial]



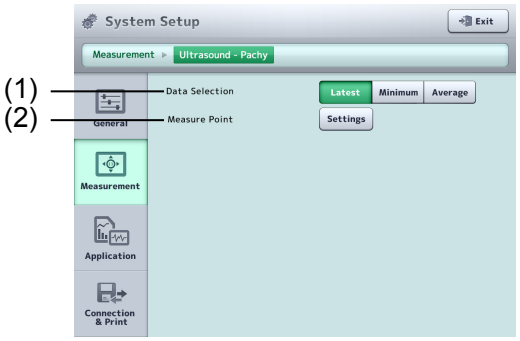
(Fig. 1)

(1) Default fitting formula
Set the fitting formula for normal operation.
Contact / Immersion

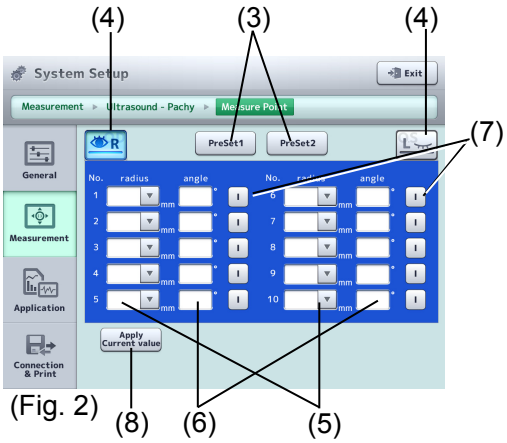
(2) Fix light
Select whether the fix light in the biometry probe is turned on or off.
ON / OFF

(3) Setting Velocity
Mean Velocity (M/V) / Sectional Velocity (S/V)

[Ultrasound – Pachy]



(Fig. 1)



(Fig. 2)

(1) Data Selection Method

Select the measurement data type to be displayed.
Latest / Minimum / Average

(2) Measure Point

Opens the measurement setup screen (Fig. 2).

(3) PreSet1 / PreSet2

Changes the selected preset measurement point.

(4) Eye selection

Changes the preset measurement point of the selected eye.

(5) Radius input field

Specify the radius distance from the center of the measurement point.
Touch the input field. The keypad appears. Touch the "▼" on the right of the input field The pull down menu appears. Select CCT or enter the desired value using the keypad.
Input range : 0.0 - 15.0 mm

(6) Angle input field

Enter the angle from the horizontal axis at the measurement point. The key pad appears when the input field is touched.
Input range : 0 – 179

(7) S/I selection button

The mode alternates between "S" and "I" every time you touch the button.

(8) "Apply Current Value" button

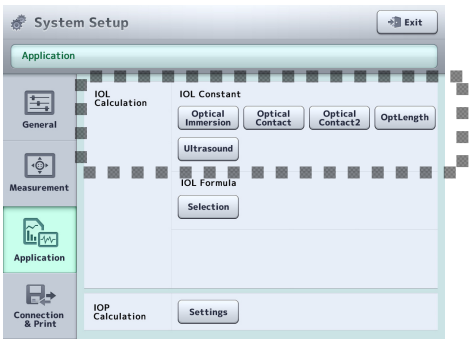
Enters the measurement points currently being used in each field on the measurement screen.

3.9.3 Application

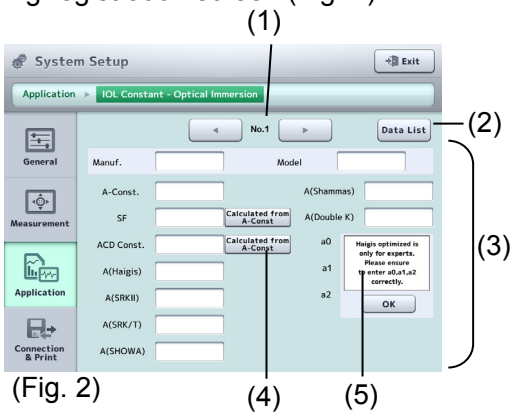
Make settings related to measurement of calculation, correction, etc.
Select the Application tab.

a) Registering IOL data

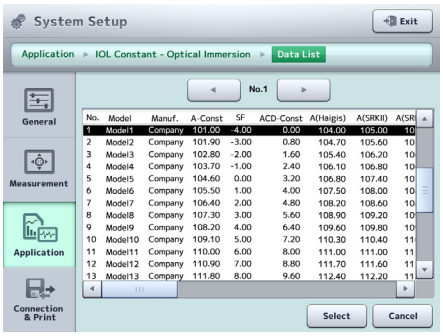
Register the IOL data for optical immersion measurement, optical contact measurement, optical contact2 measurement, optical length measurement, and ultrasound measurement.
Touch each button to open the corresponding registration screen (Fig. 2).



(Fig. 1)



(Fig. 2)



(Fig. 3)

(1) Data list No.
Set the registration number of the IOL data list.

(2) “Data List” button
The IOL data list is displayed.

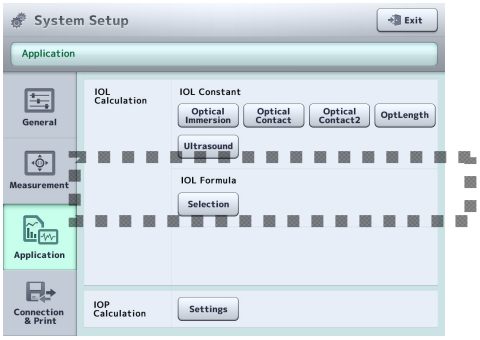
(3) IOL data input field
Enter each item. The software keyboard appears when the entry field is touched.

(4) “Calculated from A-Const” button
Calculates the values corresponding to SF and ACD constants. The calculated values are displayed in the respective input boxes.

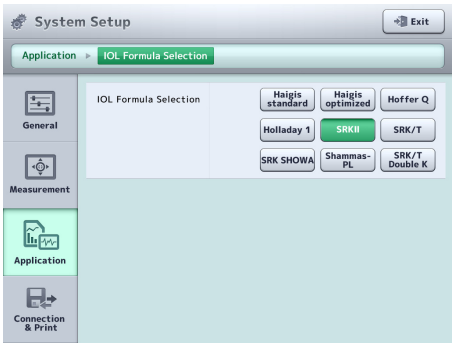
(5) Warning message
Displays warnings for determination of a0, a1, and a2.
When the “OK” button is touched, the warning message disappears and the input field appears.

b) Selecting IOL power formula

Select the IOL formula to be used on the IOL power calculation screen. The selected formulae will be displayed in the pull-down menu on the IOL power calculation screen. Touch the “Selection” button to open the IOL Formula Selection screen (Fig. 2).



(Fig. 1)



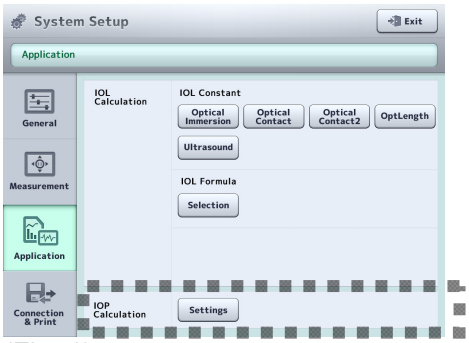
(Fig. 2)

When Haigis Standard is selected, the a1 and a2 setting fields are displayed. When SRK/T Double K is selected, the setting field for cornea equivalent refractive index (Keratometric Index KI) is displayed.

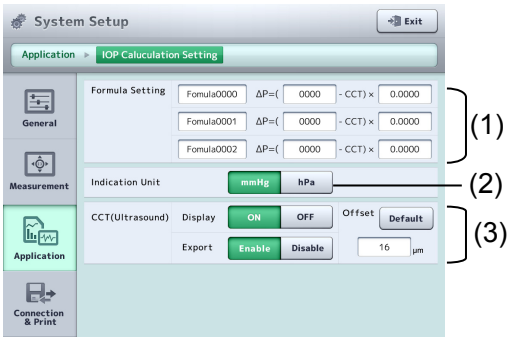
(Fig. 3)

c) Setting IOP formula

Register the intraocular pressure correction formula to be used for the intraocular pressure correction. The formula set here can be selected on the intraocular pressure correction screen. Touch the “Settings” button to open the selection screen (Fig. 2).



(Fig. 1)



(Fig. 2)

(1) Intraocular pressure correction formulas

Register the intraocular pressure correction formula to be used for the intraocular pressure correction.

		Input range
IOP correction formula name	:	Up to 10 characters
Parameter 1	:	0～1500
Parameter 2	:	0.0000～1.0000

(2) Indication Unit mmHg / hPa

(3) CCT (Ultrasound)

Set the CCT ultrasound correction value.

View	:	ON / OFF
Export	:	Enable / Disable
Offset	:	Input range 0 - 30
“Default" button	:	Set the offset value to 16 µm.

3.9.4 Connection & Print

Make settings related to connection, saving, export, and printing on this screen.
Select the Connection & Print tab.

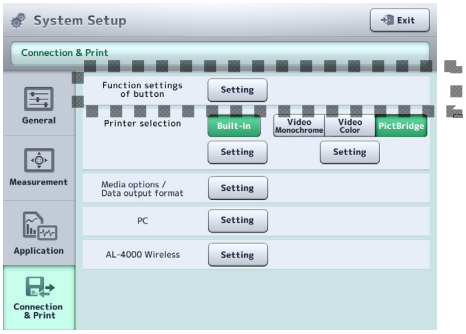
a) Setting functions of save, export, and print buttons

Assign functions to 2 buttons for saving, export, and print provided on each screen (Fig. 1).

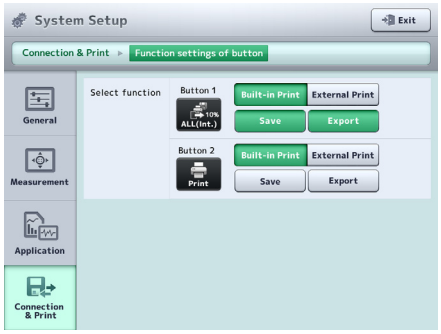
(Fig. 1)

Button 1 Button 2

Touch the “Setting” button for Function settings of button to open the System Setup screen (Fig. 3).



(Fig. 2)



(Fig. 3)

Select the function to be assigned to each of two buttons. The button icon changes according to the selections.
The symbol of the print button varies depending on the selected printer as shown below.

Built-in printer: Built-in
Video printer: Video
PictBridge printer: Pict

Export

Print

Save

Export&Save

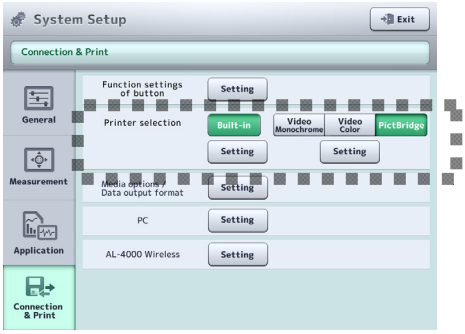
Export&Print

Print&Save

Export, print, and save

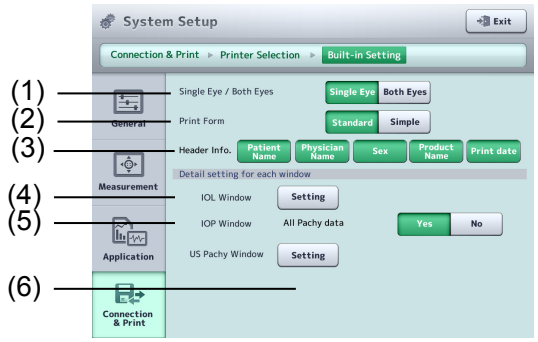
b) Selecting and setting printer

The built-in printer, video monochrome printer, video color printer, or PictBridge printer can be selected. Touch the “Setting” button to open the Setup screen for each printer. There are no setting items for the video color printer.

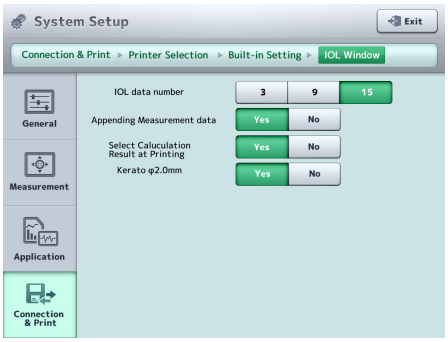


(Fig. 1)

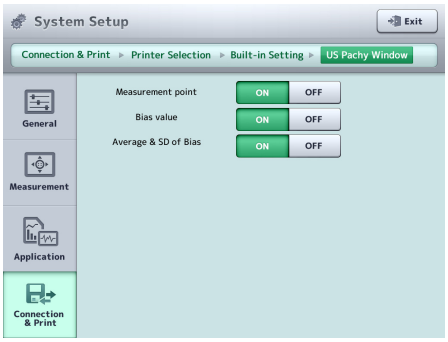
[Built-in printer setting]



(Fig. 1)



(Fig. 2)



(Fig. 3)

(1) Single Eye / Both Eyes

Set whether to print the data of the displayed eye only or the data of both eyes.

Single Eye / Both Eyes

(2) Print Form

Select the display form of printing.

Standard / Simple

(3) Header Info.

Select items to always be printed.

Patient Name / Physician Name / Sex / Product Name / Print Date

(4) IOL Window (IOL power calculation screen)

Make settings for printing from the IOL power calculation screen.

Touch the “Setting” button to open the System Setup screen (Fig. 2).

IOL data number	:	3 / 9 / 15
AppendingMeasurement data	:	Yes / No
Select Calculation Result at Printing	:	Yes / No
Karato φ 2.0mm	:	Yes / No

(5) IOP Window (intraocular pressure correction screen)

Set whether to print the measurement data on the intraocular pressure correction screen.

Yes / No

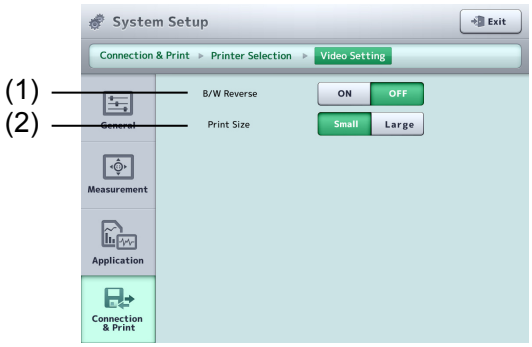
(6) US Pachy Window (ultrasound corneal thickness measurement)

Make settings for printing on the ultrasound corneal thickness measurement screen.

Touch the “Setting” button to open the System Setup screen (Fig. 3).

Measurement point (for each memory)	:	ON / OFF
Bias value (for each memory)	:	ON / OFF
Average & SD of Bias (average and standard deviation of bias value)	:	ON / OFF

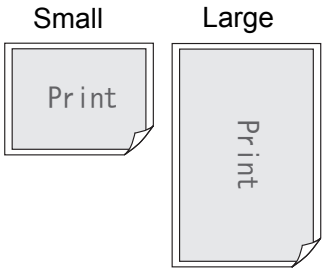
[Video monochrome printer setting]



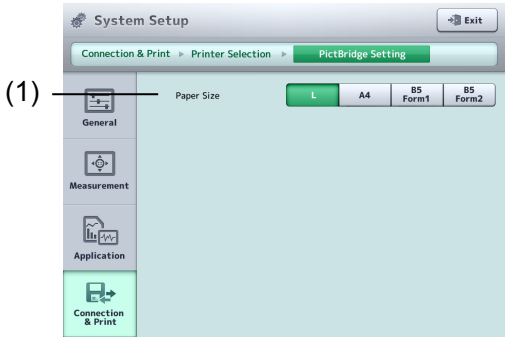
(Fig. 1)

(1) B/W Reverse (black/white reverse printing)
ON / OFF

(2) Print Size
Small / Large



[PictBridge printer setting]



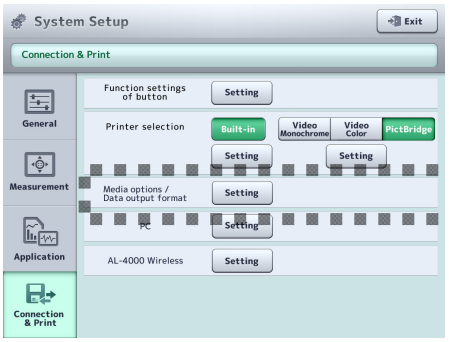
(Fig. 1)

(1) Print Size
L / A4 / B5 Form 1 / B5 Form 2
B5 Form 1: When the paper feed tray is centered.
B5 Form 2: When the paper feed tray is left-aligned.

c) Media options / Data output format

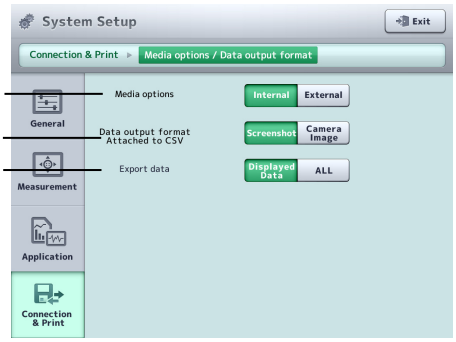
Note ■ ***Some USB flash memories are not recognized when connected to this instrument.***

Select the storage and set the output format. Touch the “Setting” button to open the System Setup screen (Fig. 2).



(Fig. 1)

(1)
(2)
(3)

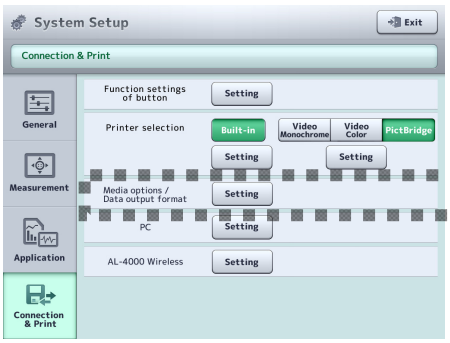


(Fig. 2)

(1) Media options
Internal : Saves the data to the instrument’s built-in SD card.
Max. capacity to be saved: 16 GB
External : Saves the data to an external USB flash memory connected to the instrument.
(2) Data output format
Screen shot: Outputs a captured image of the screen.
Camera image: Outputs a CCD image.
(3) Export data
Displayed data : Exports only the displayed measurement data.
ALL : Exports all measurement data.

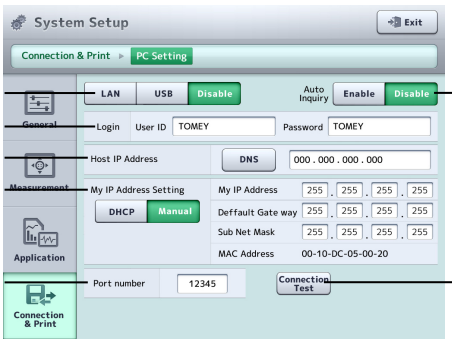
d) PC (PC connection)

Make connection settings to export data to a personal computer with TOMEY Link or Data Transfer installed. Touch the “Setting” button to open the System Setup screen (Fig. 2).



(Fig. 1)

(1)
(3)
(4)
(5)
(6)



(2)
(7)

(Fig. 2)

(1) Connection permission and selection of cable type

LAN : Use a LAN cable for connection.
When “LAN” is selected here, all items listed on this screen need to be set.

USB : Use a USB cable for connection.
Set the Login User ID and Password. Items other than the above do not need to be set.

Disable : Not connected with PC.

(2) Auto Inquiry

Set whether to automatically retrieve the patient ID.

(3) Login TOMEY Link

Set the user ID and password to log in to the TOMEY Link. Maximum number of characters to be entered for the user ID or password is 16.

(4) Host IP address

Set the IP address of the PC to be connected. Touch the “DNS” button to specify the PC name. A DNS server must be running in the LAN environment to enable connection using the DNS.
Touch the input field to display the keyboard.

(5) My IP Address Setting

Selects either of DHCP (dynamic IP) or MANUAL (static IP) in the IP Setting Type. When “Manual” is selected, set My IP Address, Sub Net Mask, and Default Gateway.

(6) Port number

A port number can be set.
Input range : 0 – 65535
Default setting : 80

(7) "Connection Test" button

Performs a connection test.

Setting examples

■ **When only this instrument and the TOMEY Link Server or a computer running Data Transfer are connected to the network, the following settings can be used.**

1) Check the computer IP address.
Check and record the IP address and subnet mask of the computer with DATA Transfer installed. Refer to the DATA Transfer operation manual for details.
2) Set settings on the Instrument.
The settings shown in the table below describe an example when the IP address of the computer with DATA Transfer installed is “192.168.2.128” and the subnet mask is “255.255.255.0.” The IP setting method in this case is Manual.

	Computer settings				Instrument settings			
(Local) IP address	192	168	2	128	192	168	2	129
	Check these on the DATA Transfer screen.				Same value as computer setting			(＊1)
Subnet mask	255	255	255	0	255	255	255	0
	Check these on the DATA Transfer screen.				Same value as computer setting			
Default gateway	-------				0	0	0	0
					All 0			
Host IP address	-------				192	168	2	128
					IP address of computer			

*1: An arbitrary number from 1 to 255 excluding numbers used by the computer (128 in this example)

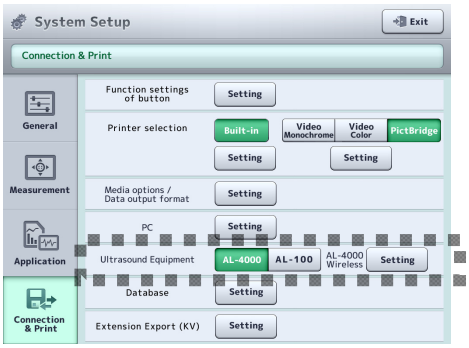
e) Selection of ultrasound biometer and AL-4000 Wireless setting

Select the ultrasound biometer and make settings for wireless communication with the ultrasound measurement unit AL-4000. Connection can be established automatically upon startup of the instrument when the information of the AL-4000 to be connected is registered in the connection location list and “Permit” is selected for Wireless Communication.

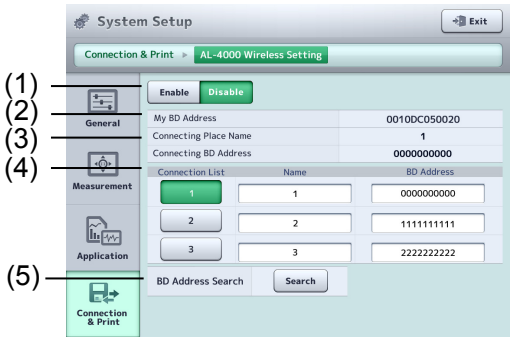
Note

■ ***While the System Setup screen is opened on a device during wireless communication with AL-4000, operation of the other device is disabled. Disable wireless communication and press the measurement button to open the System Setup screen on both devices at the same time.***

Select the model of the ultrasound biometer.When AL-4000 is selected, settings for wireless communication can be made.



(Fig. 1)



(Fig. 2)

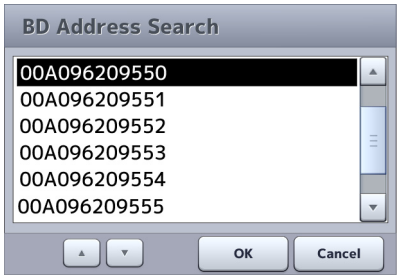
(1) Connection permission
Enable / Disable

(2) My BD Address
The BD address of this instrument is displayed.

(3) Connecting Place Name; Connecting BD Address
The connecting location name and BD address currently connected are displayed. These fields are blank when nothing is connected.

(4) Connection List
Register connecting locations. Touch the Name or BD Address field to open the keyboard. Select the number to set the item as the connecting location.

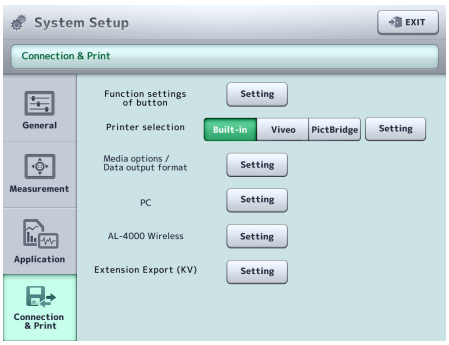
(5) BD Address Search
Touch the “Search” button to search for ultrasound measurement units AL-4000 around the instrument and display their BD addresses. (Fig. 3)
Touch the “OK” button to add the selected BD address to the Connection List.



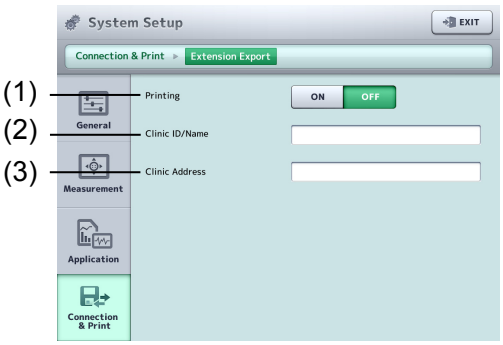
(Fig. 3)

f) Extension Export

Sets whether to output information related to the clinic and measurement techniques.



(Fig. 1)



(Fig. 2)

(1) Printing
ON / OFF

(2) Clinic ID / Name
Set the clinic ID and name.

(3) Clinic Address
Set the address of the clinic.

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4. TECHNICAL INFORMATION

4.1 IOL power calculation formula

4.1.1 Haigis Standard / Haigis optimized

1. Implanted IOL power (D)

$$P = \frac{1000na}{L-d} - \frac{na}{\frac{na}{z} - \frac{d}{1000}}$$

Where:

$$Z = DC + \frac{REF}{1 - \frac{REF \cdot V}{1000}}$$

d = a0 + a1·ACD + a2·L (ACD ≠ 0)

d =(a0 – 0.241·a1) + (a2 + 0.139·a1)L (ACD = 0)

a0 = 0.62467A – 72.434….*

$$DC = \frac{1000(nc-1)}{RC}$$

2. Estimated refractive power after surgery (D)

$$REF_{iol} = \frac{1000(1000Y - DC \cdot X)}{V(1000Y - DC \cdot X) + 1000X}$$

Where:

X = d2·P + 1000L·na - d·L·P

Y = na (1000·na-L·P + d·P)

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 1.3315

A : A-Constant

RC : Average radius of corneal curvature (mm)
= （r1 + r2）/2

R : Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

K : Corneal refractive power (D)

KI : Cornea equivalent refractive index

DC : Average corneal refractive power (D)

L : Axial length

ACD : Anterior chamber depth (mm)

REF : Target Ref. after surgery (D)

V : Vertex distance (mm)

= 12

P : Implanted IOL power (D)

a1 : 0.4…※

a2 : 0.1…※

* The Haigis optimized formula uses the registered a0, a1, and a2 for calculation.

3. Personal A-Constant

$$A = \frac{d - a1 \cdot ACD - a2 \cdot L + 72.434}{0.62467} \qquad \text{(ACD≠0)}$$

$$A = \frac{d - L(a2 + 0.139 \cdot a1) + 0.241 \cdot a1 + 72.434}{0.62467}$$

(ACD=0)

Where:

$$d = \frac{P(L \cdot z + 1000\,na) - \sqrt{P^2(L \cdot z + 1000\,na)^2 - 4P \cdot z(1000\,L \cdot na \cdot z + 1000\,L \cdot na \cdot P - 1000^2 \cdot na^2)}}{2P \cdot z}$$

$$Z = DC + \frac{AREF}{1 - \frac{AREF \cdot V}{1000}}$$

$$DC = \frac{1000(nc - 1)}{r}$$

AREF : Refractive power of eye after surgery (D)

4.1.2 Hoffer® Q formula

1. Implanted IOL power (D)

$$P = \frac{1336}{L - C - 0.05} - \frac{1.336}{\frac{1.336}{K + R} - \frac{C + 0.05}{1000}}$$

Where:

$$R = \frac{Rx}{1 - 0.012Rx}$$

2. Target Ref. after surgery (D) when wearing glasses

$$Rx = \frac{R}{1 + 0.012R}$$

Where:

$$R = \frac{1.336}{\frac{1.336}{\frac{1336}{L - C - 0.05} - P} + \frac{C + 0.05}{1000}} - K$$

C : Predicted anterior chamber depth after surgery (ACD)

= X + Y

Where:

X = C1 + 0.3 × (L – 23.5) + $(\tan K)^2$

Y = 0.1M × $(23.5 - L)^2$ × tan{0.1$(G - L)^2$}

- 0.99166

L ≦ 23.0 → M = + 1, G = 28

L > 23.0 → M = - 1, G = 23.5

L > 31.0 → L = 31

L < 18.5 → L = 18.5

P : Implanted IOL power (D)

L : Axial length (mm)

C1 : ACDcon or Personal ACD (mm)

K : Average corneal refractive power (D)

= (K1 + K2)/2

r : Radius of corneal curvature (mm)

= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

Rx : Target Ref. after surgery (D) when wearing glasses

3. Personal ACD

$$ACD = \frac{L + N - \sqrt{(L - N)^2 + \frac{4 \cdot 1336(N - L)}{P}}}{2} - 0.05$$

Where:

$$N = \frac{1336}{K + R} \qquad R = \frac{AREF}{1 - 0.012 AREF}$$

AREF : Refractive power of eye after surgery (D)

4.1.3 Holladay 1

1. Implanted IOL power (D)

$$P = \frac{1000\ na\ \{X - 0.001\ REF\ (V \cdot X + L2 \cdot r)\}}{(L2 - C2 - SF)[Y - 0.001\ REF\ \{V \cdot Y + r(C2 + SF)\}]}$$

2. Predicted refractive power after surgery (D)

$$REF_{iol} = \frac{1000\,na \cdot X - P \cdot Q \cdot Y}{na(V \cdot X + L2 \cdot r) - 0.001P \cdot Q\{V \cdot Y + r(C2 + SF)\}}$$

Where:

X : na · r – L2 (nc – 1)

Y : na·r - (nc - 1)(C2 + SF)

Q : L2 – C2 -SF

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 4/3

L : Axial length (mm)

K : Average corneal refractive power (D)
= (K1 + K2)/2

r : Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

SF : Distance from the iris surface to the optical center of the implanted IOL (mm)

REF : Target Ref. after surgery (D)

V : Vertex distance (mm)
= 12

P : Implanted IOL power (D)

L2 : Corrected axial length (mm)
= L + 0.2

C2 : Anatomic anterior chamber depth; distance from the corneal vertex to the iris surface (mm)
= 0.56 + Rag – $\sqrt{Rag^{\,2} - AG^{\,2}/4}$
r < 7 → Rag = 7
r ≧ 7 → Rag = r
AG = 12.5L / 23.45
AG > 13.5 → AG = 13.5

3. Personal SF

$$SF = \{-BQ - \sqrt{BQ^2 - 4AQ \cdot CQ}\} / (2AQ) - C2$$

Where:

AQ = (nc-1) - 0.001AREF {V(nc - 1) - r}

BQ = 0.001AREF {L2·V(nc - 1) - r(L2 - V·na)}

- {L2(nc - 1) + na·r}

CQ1 = 0.001AREF[V{na·r - L2(nc - 1)} + L2·r]

CQ2 = 1000na{na·r – L2(nc - 1) - CQ1}/P

CQ3 = L2·na·r-0.001AREF·L2·V·r·na

CQ = CQ3-CQ2

AREF : Refractive power of eye after surgery (D)

4. Corresponding SF

SF = 0.5663A - 65.60

or

SF = 0.9704 ACDcon – 3.595

Where:

A : A-Constant

4.1.4 SRK-II formula

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = A1 - 0.9K - 2.5L$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = P_{emme} - REF \cdot CR$$

3. Predicted refractive power after surgery (D)

$$REF_{iol} = (P_{emme} - P) / CR$$

Where:

L < 20.0	→ A1 = A +3
20.0 ≦ L < 21.0	→ A1 = A +2
21.0 ≦ L < 22.0	→ A1 = A +1
22.0 ≦ L < 24.5	→ A1 = A
24.5 ≦ L	→ A1 = A – 0.5

P_{emme} ≦14 → CR = 1.00

P_{emme} > 14 → CR = 1.25

A : A-Constant

K : Average corneal refractive power (D)
= (K1 + K2)/2

r : Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

L : Axial length (mm)

P : Implanted IOL power (D)

REF : Target Ref. after surgery

4. Personal A-Constant

A = P + AREF · RF + 2.5L + 0.9K - COR

Where:

AREF : Eye refractive power after surgery (D)

RF : Refractive factor

P > 16 → RF = 1.25

P ≦16 → RF = 1

COR : Correction

L < 20.0 → COR = 3

20.0 ≦L < 21.0 → COR = 2

21.0 ≦L < 22.0 → COR = 1

22.0 ≦L < 24.5 → COR = 0

24.5 ≦L → COR = -0.5

4.1.5 SRK/T formula

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = \frac{1000 \quad na \cdot X}{(L1 - C1)Y}$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = \frac{1000 \ na \{X - 0.001 \ REF \ (V \cdot X + L1 \cdot r)\}}{(L1 - C1)\{Y - 0.001 \ REF \ (V \cdot Y + C1 \cdot r)\}}$$

3. Predicted refractive power after surgery (D)

$$REF_{iol} = \frac{1000\, na \cdot X - P \cdot Y(L1 - C1)}{na(V \cdot X + L1 \cdot r) - 0.001P(L1 - C1)(V \cdot Y + C1 \cdot r)}$$

Where:

X = na · r – L1 (nc – 1)

Y = na · r – C1 (nc – 1)

L1 : Visual axial length (mm)
= L + (0.65696-0.02029L)

L : Axial length (mm)

REF : Target Ref. after surgery (D)

W : Calculated corneal diameter (mm)
= -5.41 + 0.58412LC + 0.098K

LC : Corrected axial length (mm)
L ≦24.2 → LC = L
L > 24.2 → LC = -3.446 + 1.716L - 0.0237L^2

C1 : Estimated anterior chamber depth after surgery (mm)
= H + Ofst.

Ofst :Calculated distance from the iris surface to the optical surface of the implanted IOL (including corneal thickness) (mm)
= ACD const – 3.336
= (0.62467A – 68.747) - 3.336

H : Height of cornea dome (mm)
$= r - \sqrt{r^2 - W^2/4}$

A : A-Constant

K : Average corneal refractive power (D)
= (K1 + K2)/2

r :Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

P : Implanted IOL power (D)

V : Vertex distance (mm)
= 12

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 1.333

4. Personal A-Constant

$$A = \left(-b + \sqrt{b^2 - 4ac}\right) / 2a$$

Where:

a : $0.62467^2\ \alpha$

b : $0.62467\ \{2\alpha\ (H - 72.083)\} + \beta\}$

c : $\alpha(H - 72.083)^2 + \beta(H\text{-}72.083) + r$

α : $P\ (1 - nc) + 0.001P \bullet AREF\ \{V\ (nc - 1) - r\}$

β : $P\ [na \cdot r + L1\ (nc - 1)$
$+ 0.001AREF\ \{L1 \cdot r + V \cdot L1\ (1 - nc) - na \cdot V \cdot r\}]$

r : $na\ [1000X - P \cdot L1 \cdot r + AREF$
$\{0.001P \cdot V \cdot L1 \cdot r - (V \cdot X + L1 \cdot r)\}]$

AREF : Refractive power of eye after surgery (D)

4.1.6 SRK SHOWA formula

1. Implanted IOL power (D)

L < 22.0	: P = A - 2.5L - 0.9K + 1.4 - 1.45REF
22.0 ≦L < 24.5	: P = A - 2.5L - 0.9K - 1.67REF
24.5 ≦L < 27.0	: P = A - 2.5L - 0.9K + 0.71 - 1.25REF
27.0 ≦L	: P = A - 2.5L - 0.9K - 1.69REF - 1.69

2. Predicted refractive power after surgery (D)

L < 22.0	: R = (A - 2.5L - 0.9K + 1.4 - P)/1.45
22.0 ≦L < 24.5	: R = (A - 2.5L - 0.9K - P)/1.67
24.5 ≦L < 27.0	: R = (A - 2.5L - 0.9K + 0.71 - P)/1.25
27.0 ≦L	: R = (A - 2.5L - 0.9K - 1.69 - P)/1.69

L : Axial length

K : Average corneal refractive power (D)
= (K1 + K2)/2

r : Radius of corneal curvature (mm)
= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

REF : Target Ref. after surgery (D)

A : A-Constant

P : Implanted IOL power (D)

3. Personal A-Constant

L < 22.0 : A = P + 2.5L + 0.9K - 1.4 + 1.45AREF

22.0 ≦L < 24.5 : A = P + 2.5L + 0.9K + 1.67AREF

24.5 ≦L < 27.0 : A = P + 2.5L + 0.9K - 0.71 + 1.25AREF

27.0 ≦L : A = P + 2.5L + 0.9K + 1.69AREF + 1.69

AREF: Eye refractive power after surgery (D)

4.1.7 Shammas-PL formula

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = \frac{1336}{L - 0.1(L-23) - (C + 0.05)} - \frac{1}{\frac{1.0125}{Kc} - \frac{C + 0.05}{1336}}$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = \frac{1336}{L - 0.1(L-23) - (C + 0.05)} - \frac{1}{\frac{1.0125}{Kc + REFc} - \frac{C + 0.05}{1336}}$$

3. Predicted refractive power after surgery (D)

$$REFc_{iol} = \frac{1.0125 \times 1336 \left[1336 - P\{Lc - (C + 0.05)\}\right]}{1336 \cdot Lc - P(C + 0.05)\{Lc - (C + 0.05)\}} - Kc$$

L : Axial length (mm)

C = pACD = (0.5835 × A) - 64.40

A : A-Constant

Kc = 1.14 × K - 6.8

K : Average corneal refractive power (D)

= (K1 + K2)/2

R : Radius of corneal curvature (mm)

= {(KI - 1) × 1000}/K

KI : Cornea equivalent refractive index

REFc : Refractive power at corneal refractive surface

$$= \frac{1000}{\frac{1000}{REF} - VD}$$

REF : Target Ref. after surgery (D)

P : Implanted IOL power (D)

Lc = L-0.1(L-23)

VD : Vertex distance (mm)

= 12

4. Personal A-Constant

$$A = \frac{1}{0.5835}\left[\frac{1336\ \cdot a}{2} + \frac{Lc}{2} - \frac{1336}{2}\sqrt{\left(a + \frac{Lc}{1336}\right)^2 - \frac{4}{1336}\left\{Lc\left(a + \frac{1}{P}\right) - \frac{1336\ \cdot a}{P}\right\}} - 0.05 + 64.4\right]$$

$$a = \frac{1.0125}{Kc + AREFc}$$

AREFc: Eye refractive power at corneal refractive surface

$$= \frac{1000}{\frac{1000}{AREF} - VD}$$

AREF: Eye refractive power after surgery (D)

4.1.8 SRK/T Double K

1. Implanted IOL power (D) for emmentropization

$$P_{emme} = \frac{1000\ \ na\ \cdot X}{(L1\ -\ C1)Y}$$

2. Implanted IOL power (D) for ametropia

$$P_{amet} = \frac{1000\ na\left\{X - 0.001\ REF\ \left(V \cdot X + L1 \cdot r_{post}\right)\right\}}{(L1 - C1)\left\{Y - 0.001\ REF\ \left(V \cdot Y + C1 \cdot r_{post}\right)\right\}}$$

3. Predicted refractive power after surgery (D)

$$REF_{iol} = \frac{1000\,na \cdot X - P \cdot Y(L1 - C1)}{na\left(V \cdot X + L1 \cdot r_{post}\right) - 0.001P(L1 - C1)\left(V \cdot Y + C1 \cdot r_{post}\right)}$$

Where:

X = na・ r post – L1 (nc – 1)

Y = na・ r post – C1 (nc – 1)

L1 : Visual axial length (mm)
= L + (0.65696-0.02029L)

L : Axial length (mm)

C1 : Estimated anterior chamber depth after surgery (mm)
= H + Ofst.

Ofst : Calculated distance from the iris surface to the optical surface of the implanted IOL (including corneal thickness) (mm)
= ACD const – 3.336
= (0.62467A – 68.747) - 3.336

H : Height of cornea dome (mm)

$$= r_{pre} - \sqrt{r_{pre}^2 - W^2/4}$$

W : Calculated corneal diameter (mm)
= -5.41 + 0.58412LC + 0.098K_{pre}

LC : Corrected axial length (mm)
L ≦24.2 → LC = L
L > 24.2 → LC = -3.446 + 1.716L - 0.0237L^2

A : A-Constant

K_{pre} : Average corneal refractive power (D) before refractive correction surgery
= ($K1_{pre}$ + $K2_{pre}$)/2

r_{pre} : Radius of corneal curvature (mm) before refractive correction surgery
= {(KI - 1) × 1000}/ K_{pre}

KI : Cornea equivalent refractive index

K_{post} : Average corneal refractive power (D) after refractive correction surgery
= ($K1_{post}$ + $K2_{post}$)/2

r_{post} : Radius of corneal curvature (mm) after refractive correction surgery
= {(KI - 1) × 1000}/ K_{post}

P : Implanted IOL power (D)

na : Aqueous humor and vitreous refractive index
= 1.336

nc : Corneal reflective index
= 1.333

REF : Target Ref. after surgery (D)

V : Vertex distance (mm)
= 12

4. Personal A-Constant

$$A = \left(-b + \sqrt{b^2 - 4ac}\right) / 2a$$

Where:

a : $0.62467^2\alpha$

b : 0.62467 {2α(H – 72.083)} +β}

c : $\alpha(H - 72.083)^2 + \beta(H\text{-}72.083) + r$

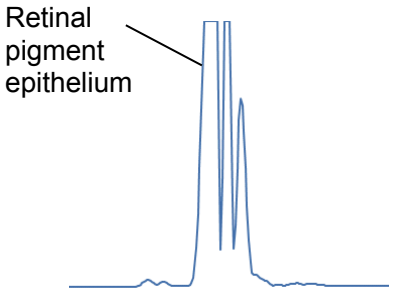
$$\alpha : P(1 - nc) + 0.001P \cdot AREF\{V(nc - 1) - r\}$$

$$\beta : P[na \cdot r + L1(nc - 1) + 0.001AREF\{L1 \cdot r + V \cdot L1(1 - nc) - na \cdot V \cdot r\}]$$

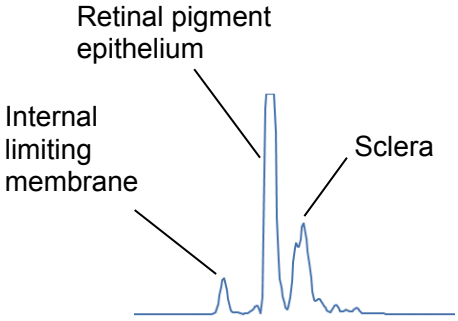
$$r : na[1000X - P \cdot L1 \cdot r + AREF\{0.001P \cdot V \cdot L1 \cdot r - (V \cdot X + L1 \cdot r)\}]$$

AREF : Refractive power of eye after surgery (D)

4.2 Verification when measuring axial length



（Fig.1） Retina waveform example 1



(Fig.2) Retina waveform example 2

OA-2000 measures the distance from the lacrimal fluid on the corneal surface to the retinal pigment epithelium (RPE) as the axial length.
Normally, the waveform height and width of the internal limiting membrane and choroid are smaller than those of the retinal pigment epithelium. (Fig. 1)

Reflection from the internal limiting membrane (ILM) may be received depending on the condition of the retina. (Fig. 2)

If the waveform of the internal limiting membrane is larger than that of the retinal pigment epithelium, the resultant axial length may be shortened by 0.15 – 0.35 mm.

If values of the axial length are varied or individual waveforms seem to show that the retinal pigment epithelium was not correctly captured, thoroughly evaluate the measurement data, referring to the following points.
- Take measurement again.
- Compare the data with the measurement taken in ultrasound A mode.
- Check for the presence of ocular fundus diseases.

4.3 Ultrasound conversion formula

The axial length measurement displayed in Contact mode or Immersion mode of OA-2000 is the value calculated by converting the optically obtained axial length to an ultrasound axial length value, using a correction formula developed based on clinical results. Therefore, the converted ultrasound axial length value includes measurement errors due to the difference between the optical measurement principle/method and ultrasound measurement principle/method.

- Formula for conversion to ultrasound axial length in Contact mode

  AXIAL(Contact) = {OptLength － 1.4687} / 0.9581

  When {OptLength - AXIAL(Contact)} ≧ 0.75mm
  AXIAL(Contact) = OptLength － 0.75

- Formula for conversion to ultrasound axial length in Immersion mode

  AXIAL(Immersion) = {OptLength － 1.3304} / 0.9573

  OptLength = OPL/Naxl
  OPL : Optical path length
  Naxl : Average refractive index of eye

Difference between optical and ultrasound measurement principles/methods

- Retina thickness

  The thickness from the corneal epithelium to the retinal pigment epithelium is measured by the optical method, while the thickness from the corneal epithelium to the internal limiting membrane is measured by the ultrasound method. Therefore, the retina thickness and axial length measured by the optical method become longer than the values measured by the ultrasound method.

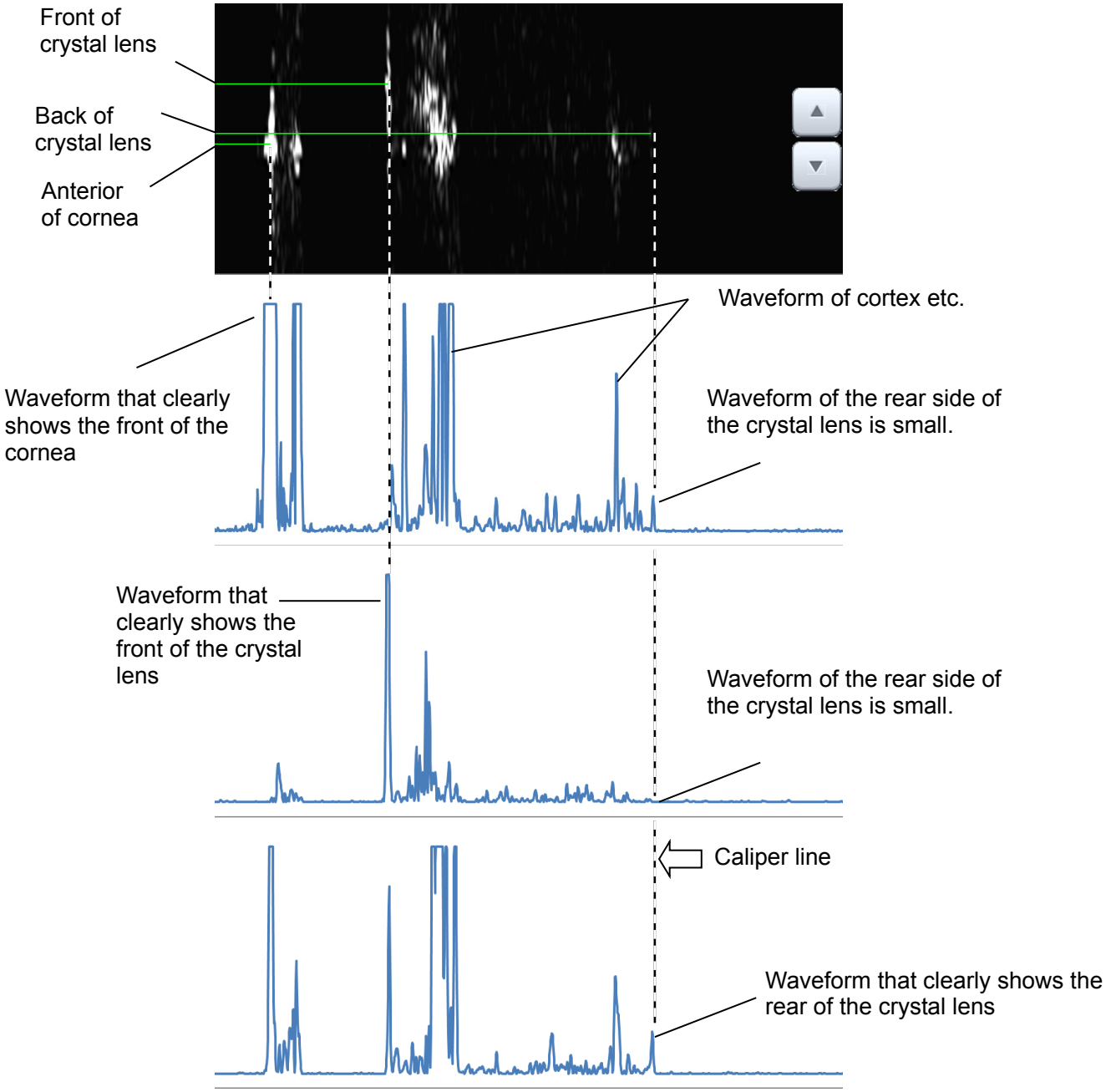
- Pressure on retina

  The optical method performs non-contact measurement, but the probe contacts the retina directly or indirectly. Therefore, the axial length measured by the ultrasound method tends to be shorter due to pressure on the retina.

- Measurement axis

  Since the optical method requires fixing the patient's sight to the light source, a stable visual axis can be captured during measurement. On the other hand, although the fixation light is used for the ultrasound method, the optic axis where the reflection of the retina waveform becomes the strongest is captured during actual measurement.

4.4 Verification when measuring anterior chamber depth and crystal lens thickness



Since there are many waveforms of the cortex etc. of the crystal lens when measuring an eye with cataracts, the front and rear of the crystal lens may not be captured.

In this case, adjust the waveform display line on the scanned image up and down, find and display the position where the largest waveforms are shown, and move the caliper line to the point of the front of the crystal lens.

4.5 Corneal irregular astigmatism index

Corneal irregular astigmatism index

This is the index that simply quantitates the data of the corneal irregular astigmatism which cannot be found by ordinary keratometer measurements (K1, K2, and AX) according the keratometory image. There are 2 indexes (KAI and KRI) as shown below, and each of them shows the level of irregular astigmatism.

KAI (Kerato-Asymmetry Index)
One of the corneal irregular astigmatism indexes which shows asymmetry of the cornea. This index is calculated from the discrepancy between the center of the approximate ellipse of the keratometer measurement point and the XY alignment measurement point equivalent to the corneal vertex position. The value increases for asymmetrical corneal shape such as when a part of cornea protrudes like keratoconus.

KRI (Kerato-Regularity Index)
One of the corneal irregular astigmatism that indicates the regularity (irregularity) of the cornea. This index is calculated from the discrepancy between the keratometer measurement point and its approximate ellipse. The value increases when the corneal shape is irregular such as eyes with corneal transplantation or CL-induced problems.

5. INSPECTION AND MAINTENANCE

5.1 Warranty

One-Year Limited Warranty
The seller warrants this product to be free from defects in material and workmanship under the normal use of this product for one (1) year or other term complying with local regulations from the date of invoice issued by Seller to the original purchaser.
Lamps, paper and other consumable items shall not be covered by this warranty. This warranty also shall NOT apply if the product has not been installed, operated or maintained in accordance with the INSTRUCTION MANUAL of Tomey Corporation (here in after called “Tomey”). Neither seller not Tomey shall be liable for any damages caused by purchaser's failure to follow instruction for proper installation, use and maintenance of product.
This warranty is only applicable to the new product and DOES NOT cover any damage resulting from or caused by accident or negligence, abuse, misuse, mishandling, improper modification of this product, by persons other than personnel duty authorized by Tomey, not to a product whose serial number or batch number is removed, altered or effaced.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED (INCLUDING SPECIFICALLY, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING,
ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE), AND ALL OTHER OBLIGATION AND LIABILITY ON THE PART OF SELLER AND TOMEY. NEITHER SELLER NOR TOMEY SHALL BE LIABLE FOR INCIDENTAL,
CONSEQUENTIAL OR SPECIAL DAMAGES UNDER ANY CIRCUMSTANCES OR FOR MORE THAN REPAIR,
REPLACEMENT OR REFUND OF THE PURCHASE PRICE OF DEFECTIVE GOODS.

5.2 Operation life

This instrument is designed to have an operation life of 8 years when operated under the appropriate environment and it is adequately inspected and serviced.

5.3 Inspection

Note

- ***When there is a problem, measurement may not be performed correctly. Contact Tomey or our local distributor immediately for repair.***
- ***When measuring the imitation eyes, check that there is no dust or stain on them.***

To make sure that the internal functions operate correctly and performance is maintained, use the imitation eyes to check the accuracy before using the instrument.

Inspect method
Use the chin rest pins to fix the imitation eyes to the chin rest. Perform measurement in the same manner as measuring a patient's eyes.
Check that the measured values are within the range specified on the imitation eyes.

5.4 Routine maintenance

- ***Hold the plug when disconnecting the power plug from the outlet to avoid placing excessive force on the cord. Pulling the cord may damage the inner core wires, resulting in electric shock or fire.***

Note

- ***Do not use organic solvents such as thinner, benzene, or acetone to clean the instrument. These solvents may damage the surface of the instrument.***
- ***Clean the inner surface of the measurement window with a soft cloth from time to time. The measurement accuracy will deteriorate if the optical section in the instrument becomes dirty.***
- ***Place the dust cover over the main unit when not being used.***
- ***Disconnect the power cord and place the dust cover over the main unit when the instrument is not used for 1 month or longer.***
- ***Spray glass cleaner onto a soft cloth to clean the monitor on the main unit.***
- ***Gently wipe (do not rub) sections that patients directly touch, such as the forehead pad and chin rest with cotton dampened with alcohol.***
- ***Do not leave any water, chemicals, etc. remaining on the touch panel as the surface of the touch panel is vulnerable to moisture. The surface of the touch panel may be damaged and unable to maintain the appropriate performance.***

Wipe off dirt on the main unit by lightly rubbing with a well wrung cloth dampened with water and then with a dry cloth. When it is very dirty, clean it by lightly rubbing with a well wrung cloth dampened with diluted neutral detergent. Then, wipe it with a cloth dampened with water and then with a dry cloth.

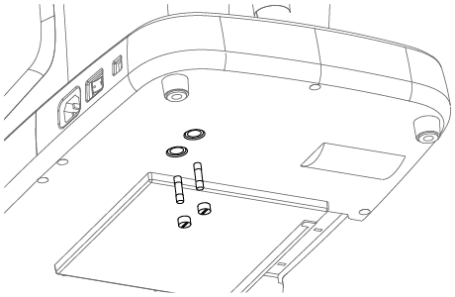
Wipe off dirt on the surface of the touch panel with a dry soft cloth. When it is very dirty, lightly wipe it with a soft cloth dampened with alcohol. Further, wipe it with a dry soft cloth to completely remove moisture.

5.5 Replacing consumables

5.5.1 Fuses

WARNING

- ***Disconnect the power cord from the outlet when replacing fuses. Otherwise you may get an electric shock, resulting in death or serious injuries.***
- ***Use fuses specifically designed for this instrument.***
- ***When the instrument does not work correctly after fuses have been replaced, there may be other causes of the problem. Turn off the instrument immediately and contact our local distributor.***



(Fig. 1)

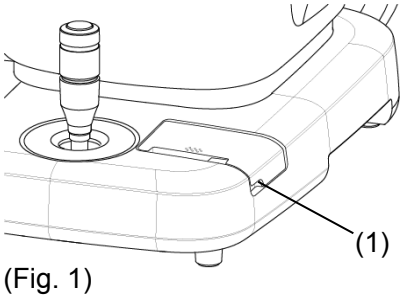
1) Turn power off and disconnect the power plug from the outlet.
2) Disconnect the power plug from the power terminal.
3) Insert a flat screwdriver or coin into the slot on the fuse case located at the bottom of the main unit. Turn the screw counterclockwise to remove it.
4) Replace the blown fuse with a new one.
5) Install the fuse holder in the reverse order of removal.

5.5.2 Printer paper

Note

- ***Always use genuine Tomey paper for the printer. Using other types of paper may cause printer failure.***
- ***Do not pull paper forcibly. Trying to pull the paper out may cause printer failure. Touch the "PRINT" button without any data stored to feed blank paper.***

Replace the paper roll according to the procedure below when red lines appear on the edges of the printer paper.



(Fig. 1)

1) Push the printer cover notch (1) upward and open it.
2) Remove the old printer paper roll and install a new roll. If the paper roll is installed in the wrong direction, nothing will be printed.
3) Close the printer cover with the end of the paper protruding 2cm from the outlet. Press the cover firmly until you hear a click.

5.6 Storing

■ ***Install the instrument in a location free of water or chemicals. Any water or chemicals entering the instrument may cause an electric shock or failure.***

■ ***Do not store the instrument in a location where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the instrument and result in fire.***

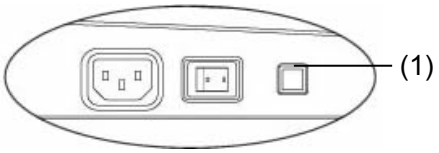
■ ***Disconnect the power cord from the outlet to ensure safety when the instrument is not operated for 1 month or longer.***

■ ***Store the instrument in a location not subject to direct sunlight, high temperature and humidity, or air containing dust, salt and/or sulfur. Otherwise, failure or malfunction may occur.***

■ ***Store the instrument in a leveled stable place free of vibration or mechanical impact. Otherwise, measurement cannot be conducted correctly. The instrument may also topple over or fall down, resulting in fire or a fatal accident.***

Note ■ ***Place the dust cover over the main unit when not being used. The measurement accuracy will deteriorate if the optical section in the instrument becomes dirty.***

Completely lower the head to the lower dead center when storing the instrument. Pressing the packing button (1) for 3 seconds automatically returns the head to the lower dead center. Turn power off.



When the instrument is not used for a while, check that the instrument is operating correctly before starting operation again.

<Storage conditions>
- Ambient temperature range : －10～＋55℃
- Relative humidity range : 10～95%

5.7 Disposal

Note ■ ***Keep the box and packing materials for use when moving or transporting the instrument.***

■ ***Keep the packing materials and the box together.***

■ ***When disposing of the main unit and/or packing materials, sort them by material type and abide by local government rules and regulations.***

■ ***A lithium battery is used in the instrument. Handling of the lithium battery varies depending on governing bodies. Follow relevant laws and local rules and regulations, or contact our local distributor or representative.***

6. TROUBLESHOOTING

Check the following first when you encounter any problems.
If the problem is not solved even after checking the applicable item listed below, contact our local distributor to request inspection and/or repair.

■ ***Do not remove the cover of the instrument. You may be directly exposed to high voltage sections.***

■ ***Do not take any actions other than those specified below.***

6.1 Common items

- **The instrument does not start when the power switch is turned on.**

Cause 1 Problem with the power plug

Solution ➡ Check that the power plug is firmly connected to the outlet. Check that there is no flaws in the power cord, such as cracks or tears.

Cause 2 Problem with the power outlet

Solution ➡ Check that power is supplied to the outlet to which the power cord is connected.

Cause 3 Blown fuse

Solution ➡ Check that fuses are not blown. If blown, replace the fuse (refer to “5.5.1 Fuses”). When the new fuse is blown again, the instrument may be out of order. Contact our local distributor to request inspection and/or repair.

- **Nothing appears on the monitor screen.**

Cause 1 The auto power off function, which automatically turns off the screen when the instrument is not operated for the specified time, has been activated.

Solution ➡ Touch the monitor screen.

Cause 2 The maintenance switch on the side is in the P position.

Solution ➡ Turned off the power, return the maintenance switch to the lower position, and then turn on the power.

- **The whole monitor screen is dark and not easy to see.**

  Cause 1 The brightness of the monitor is low.

  Solution Adjust the brightness of the screen using the brightness setting of the screen described in "3.9.1 General."

- **The clock displayed is stopped.**

  Cause 1 Stored data is displayed.

  Solution While displaying stored data,the date and time of measurement of the data is shown. When closing to the screen, current time is displayed.

- **The data cannot be printed by the video printer.**

  Cause 1 Printer paper.

  Solution Check for the remaining of printer paper. Verify that printer paper is correctly set as described in the instruction manual of the video printer.

  Cause 2 USB cable.

  Solution Verify that the USB cable is correctly connected to the main unit and the video printer. For correct connection, refer to "3.2.1 c) Connecting an external video printer".

  Cause 3 Setting the output printer

  Solution Set "Video Monochrome" to select a monocrhome printer as the output destination when pressing the PRINT button; set “Video Color” when the output destination is a color printer. Refer to “3.9.4 b) Selecting and setting printer” for setting details.

- **The brightness and color of printouts from the video printer are remarkably different from that of the screen display.**

  Cause 1 Setting of the video printer is not appropriate.

  Solution Adjust the contrast, brightness, and color as described in the instruction manual of the video printer.

- **The data cannot be printed by the built-in printer.**

Cause 1 Printer paper.

Solution Check for the remaining of printer paper. Verify that printer paper is set correctly as described in "5.5.2 Printer paper."

Cause 2 Setting the output printer

Solution Set "built-in printer" to the destination to which output is directed when "Print button" is pushed. Refer to “3.9.4 b) Selecting and setting printer” for setting details.

Cause 3 The printer cover is open.

Solution Check that the printer cover is completely closed.

Cause 4 The printer paper is not set in the correct direction.

Solution Check that the printer paper is set correctly. (Refer to "5.5.2 Printer paper")

- **A different button to the one touched on the touch panel becomes active.**

Cause 1 The touch panel is not calibrated correctly.

Solution Turn on the power, touching the touch panel. When startup of the instrument is completed while a finger is touching the touch panel, calibration of the touch panel will complete.

- **An error message “Connect the USB cable again” appears and measurement cannot be performed.**

Cause 1 The USB cable that connects AL-4000 and this instrument is disconnected.

Solution Connect the USB cable again. Communication is resumed and measurement can be started.

- **Nothing is displayed on the screen of this instrument when inputting IDs in the external ID input device.**

Cause 1 USB cable.

Solution Verify that the USB cable of the external ID input instrument is correctly connected to the main unit. For correct connection, refer to "3.2.1 d) External ID input device."

Cause 2 A screen which does not receive an ID input appears.

Solution Entry of ID from an external ID input instrument is accepted only on a screen where the patient information is displayed. Input ID after displaying such screens.

- **Data cannot be saved in the internal memory.**

Cause 1 The ID is not entered.

Solution The instrument uses the ID as a file name. Enter the ID and then save the data.

Cause 2 There is not enough space available in the internal memory. (The confirmation screen appears when attempting to save the data.)

Solution Delete unnecessary data in the internal memory and save the data again.

Cause 3 An external memory is not connected even though the storage is set to an external memory.

Solution Aconnect an external memory. Or, change the storage to the internal memory.

- **The message "Internal error occurred" is displayed and measurement cannot be performed.**

Cause 1 The SD card is not inserted properly.

Solution Remove the SD card and insert it again.

Cause 2 A problem has occured in the instrument.

Solution Reboot the instrument. If the error message is displayed again, contact our local distributer and inform them of the error number.

6.2 Optical measurement

- **Measurement cannot be performed. Stable measurements cannot be obtained. Measurements are largely different from those taken before.**

Cause 1 The measurement window is dirty.

Solution Check that the measurement window is clean.

Cause 2 A problem has occurred in the instrument.

Solution Contact our local distributor.

Cause 3 The system is not correctly calibrated.

Solution Calibrate the system.(Refer to “3.9.2 Measurement.”)

6.3 Ultrasound measurement

- **Measurement cannot be performed in Auto mode.**

Cause 1 The mode is set to Manual.

Solution Set to auto measurement (Auto or Auto quick). (Refer to “3.4.1 Setting measurement conditions.")

Cause 2 Noise is generated in the peripheral area.

Solution If there is any source of noise (devices such as a motor, laser surgical equipment, etc.) near the instrument, move it away from the instrument.

Cause 3 Patient’s sight is unstable.

Solution Use the fixlight in the biometry probe or on the chin rest to guide the sight of the patient.

Cause4 The contact section of the biometry probe is damaged.

Solution If damaged, immediately stop measurement and contact our local distributor.

- **Measurement cannot be performed in Manual mode.**

Cause 1 The mode is set to auto measurement (Auto or Auto quick).

Solution Set to Manual mode. (Refer to “3.4.1 Setting measurement conditions.")

- **Measurements are unstable or inappropriate.**

Cause 1 The converted acoustic velocity is not set appropriately.

Solution ➡ Check the setting of the converted acoustic velocity. A different converted acoustic velocity can be set for right and left eyes. Check the setting for both eyes.

Cause 2 The retina waveform gate cursor is not set in an appropriate position.

Solution ➡ Set the retina waveform gate cursor on the immediate left of the actual retina waveform. Make sure that there are no unnecessary waveforms between the retina gate cursor and retina waveform.

- **Monitoring sound does not go off.**

Cause 1 The volume is set to "Mute (Off)" for the AL-4000 measuring unit.

Solution ➡ Set the volume to a level other than “Mute (Off)” as described in the instruction manual for the AL-4000 measuring unit.

- **Noise interferes with waveforms.**

Cause 1 Noise is generated in the peripheral area.

Solution ➡ If there is any source of noise (devices such as a motor, laser surgical equipment, etc.) near the instrument, move it away from the instrument.

7. CONSUMABLES AND OPTIONAL EQUIPMENT

The following spare parts and accessories are available from our local distributor of this instrument.
Contact our local distributor to order them.

● Printer paper
Specify the paper type as "Built-in printer paper for OA-2000."

● Chin rest paper (100 sheets/set)

● Fuse
Specify the part type as “OA-2000 fuse.”

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8. SPECIFICATIONS

8.1 Specifications

8.1.1 Optical Measurement

● Measurement range

Axial length	: 14 - 40mm
Anterior chamber depth	: 1.5 - 7.0mm
Crystalline lens thickness	: 0.5 - 6.0mm
Corneal thickness	: 0.2 - 1.2mm
Corneal curvature radius	: 5.0 - 11mm
Pupil diameter	: 1.5 - 13mm
Corneal diameter	: 7 - 16mm

● Measurement accuracy

Axial length	: ±0.03mm
Anterior chamber depth	: ±0.05mm
Crystalline lens thickness	: ±0.05mm
Corneal thickness	: ±5μm
Corneal curvature radius	: ±0.02mm(φ3 mm / φ2.5 mm)
Pupil diameter	: ±0.1mm
Corneal diameter	: ±0.3mm

● Display resolution

Axial length	: 0.01mm
Anterior chamber depth	: 0.01mm
Crystalline lens thickness	: 0.01mm
Corneal thickness	: 1μm
Corneal curvature radius	: 0.01mm

8.1.2 IOL power calculation formula

- ■ Haigis standard formula
- ■ Haigis optimized formula
- ■ Hoffer® Q formula
- ■ Holladay 1 formula
- ■ SRK-II formula
- ■ SRK/T formula
- ■ SRK SHOWA formula
- ■ Shammas-PL formula
- ■ SRK/T Double K formula

8.1.3 Main unit

Data output type	: USB-Hx2, USB-Dx2, LAN, SD Card (for Internal Database)
Display	: 10.4 inches and color TFT monitor
Dimensions and weight	: 300(W) x 490(D) x 450(H)mm Approx. 24kg
Input Voltage	: 100 - 240VAC
Frequency	: 50/60Hz
Power consumption	: 110VA

8.2 Energy information

Measurement light source
- ■ Maximum power 980μW

8.3 Operating environment

Operate the instrument under the following environmental conditions.
- ■ Installation : Indoors, not in direct sunlight
- ■ Temperature : +10～+35℃
- ■ Humidity : 30～90%
- ■ Atmospheric pressure : 800～1060hPa
- ■ Power fluctuation : less than 10% of normal voltage

Store the instrument under the following environmental conditions.
- ■ Temperature : -10～+55℃
- ■ Humidity : 10～95%

Transport the instrument in the instrument's box under the following environmental conditions.
- ■ Temperature : -20～+60℃
- ■ Humidity : 10～95%

8.4 Classification

Protection against electrical shock : Class I ME equipment
Applied parts : B applied parts (Forehead pad, Chin rest)
IP Code : IP30 (Main unit)
IP10 (Measurement window)
Mode of Operation : Continuous operation
Class 1 Laser Product (IEC60825-1: 2007)

8.5 Declaration of Conformity to EMC

Caution: Medical electrical equipment.

EMC (Electro Magnetic Compatibility) must be considered before any medical electrical equipment is installed or put into service. Follow the information in the accompanying documentation when installing and operating the OA-2000.

Caution: Portable or mobile RF communication equipment can effect Medical Electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emissions

Table 201

The OA-2000 is intended for use in the electromagnetic environment specified below.

The customer or the user of the OA-2000 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The OA-2000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The OA-2000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

Table 202

The OA-2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the OA-2000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test levell	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ Burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips , short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OA-2000 requires continued operation during power mains interruptions, it is recommended that the OA-2000 is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic fi eld IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE : UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration electromagnetic immunity

Table 204

The OA-2000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the OA-2000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V rms 150kHz to 80MHz	3 V rms	Portable and mobile RF communication equipment should be used no closer to any part of the OA-2000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. B Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 V/m	

Note1 : At 80MHz and 800MHz, the higher frequency range applies.
Note2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OA-2000 is used exceeds the applicable RF compliance level above, the OA-2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OA-2000.
[b] Over the frequency range 150 kHz to 80 MHz, fi eld strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the OA-2000

Table 206

The OA-2000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OA-2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OA-2000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 : At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refl ection from structures, objects and people.

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